REGISTRATION REPORT

Part B

Section 8: Environmental Fate

Detailed summary of the risk assessment

Product code: GLOB1310aH

Product name(s): Glosset Ace

Chemical active substance:

Aclonifen, 540 g/L

Flufenacet, 60g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Authorization)

Applicant: Globachem NV

Submission date: December 2021

MS Finalisation date: 25/08/2022

After commenting: 14/12/2022

Version history

When	What
December 2021	Initial submission by the applicant for approval of new product.
August 2022	First zRMS PL evaluation
December 2022	Corrections made by zRMS PL after commenting round

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8 Fate and behaviour in the environment (KCP 9)

General comment zRMS
The following data and information were provided by the applicant Globalchem NV and have been submitted as a dRR. This document provides the results of the assessment of the zRMS. All comments of the zRMS there are in the "greyboxes".

8.1 Critical GAP and overall conclusions

Table 0-1: Critical use pattern of the formulated product

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1-6	PL BE CZ DE HU IE RO SI SK	Winter cereals Winter Wheat (TRZAW) Winter Barley (HORVW) Winter Oat (AVESW) Winter Rye (SECCW) Winter Triticale (TTLWI) Winter Durum Wheat (TRZDW)	F	Annual weeds (BBBBB)	Normal down-ward spraying	BBCH 00-09 (Sep-Dec)	a) 1 b) 1	/	a) 1.5 L/ha b) 1.5 L/ha	a) 0.810 kg Aclonifen/ha + 0.090 kg Flufenacet/ha b) 0.810 kg Aclonifen/ha + 0.090 kg Flufenacet/ha	150-300	Not rele-vant, see application stage	/	A
7-12	PL BE CZ DE HU IE RO SI SK	Winter cereals Winter Wheat (TRZAW) Winter Barley (HORVW) Winter Oat (AVESW) Winter Rye (SECCW) Winter Triticale (TTLWI) Winter Durum Wheat	F	Blackgrass (ALOMY)	Normal down-ward spraying	BBCH 00-09 (Sep-Dec)	a) 1 b) 1	/	a) 2 L/ha b) 2 L/ha	a) 1.08 kg Aclonifen/ha + 0.120 kg Flufenacet/ha b) 1.08 kg Aclonifen/ha + 0.120 kg Flufenacet/ha	200-300	Not rele-vant, see application stage	/	A

		(TRZDW)												
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
Minor uses according to Article 51 (zonal uses)														
Minor uses according to Article 51 (interzonal uses)														

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 “Conclusion”

A	Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

Table 0-2: Assessed (critical) uses during approval of Aclonifen concerning the Section Environmental Fate

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	EU	Sunflower	F	Monocot and dicot weeds	Overall spray	Pre-emergence	a) 1 b) 1	/	0.6-1.2 L/ha	2.4 kg as/ha	200-400	/	

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Table 0-3: Assessed (critical) uses during approval of Flufenacet concerning the Section Environmental Fate (Review Report 7469/VI/98 Final July 2003)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	EU	Corn	F	Annual grass weeds	Overall spray	Pre-emergence	a) 1 b) 1	/	a) 1 b) 1	a) 0.60 b) 0.60	200-400	/	
2	EU-S	Soybean, sun-flower	F	Annual grass weeds	Overall spray	Pre-emergence	a) 1 b) 1	/	a) 1 b) 1	a) 0.60 b) 0.60	200-400	/	
3	EU	Winter cereals	F	Annual grass weeds	Overall spray	Early post autumn at the 2nd leaf stage of the grass weeds	a) 1 b) 1	/	a) 0.4 b) 0.4	a) 0.240 b) 0.240	200-400	/	

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

General comment zRMS

Glosset Ace (product code: GLOB1310aH) is a suspension concentrate containing 540 g/L aclonifen and 60 g/L of flufenacet for use as a pre-emergence herbicide in winter cereals.

Aclonifen (2-chloro-6-nitro-3-phenoxyaniline; CAS No 74070-46-5) is recognised as approved for use in plant protection products under Regulation (EC) No 1107/2009 in Annex of Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 with the expiration of approval on 31 July 2019. However this approval period was extended to 31 July 2023 by Commission Implementing Regulation (EU) 2022/708 of 5 May 2022.

Flufenacet (4′-fluoro-N-isopropyl-2-[5- (trifluoromethyl)-1,3,4-thiadiazol-2-yloxy]acetanilide; CAS No 142459-58-3) is recognised as approved for use in plant protection products under Regulation (EC) No 1107/2009 in Annex of Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 with the expi-

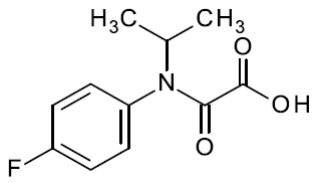
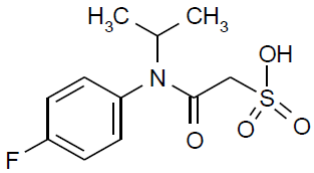
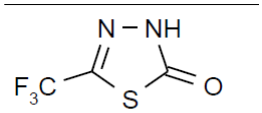
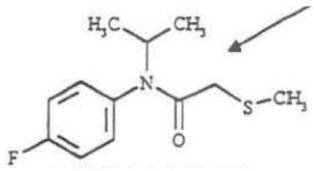
ration of approval on 31 December 2013. However this approval period was extended to 31 October 2022 by Commission Implementing Regulation (EU) 2021/1449 of 3 September 2021.

For aclonifen and flufenacet only uses as herbicide may be authorised.

8.2 Metabolites considered in the assessment

For aclonifen, no metabolite was found in amounts triggering exposure assessment.

Table 0-1: Metabolites of Flufenacet potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
FOE oxalate (M1)	225.2 g/mol		Soil 15.6%	PEC_{gw}: leaching potential to groundwater PEC_{soil}: risk for soil organisms $PEC_{sw/sed}$: risk for aquatic organisms
FOE sulfonic acid (M2)	275.3 g/mol		Soil 26.3%	PEC_{gw}: leaching potential to groundwater PEC_{soil}: risk for soil organisms $PEC_{sw/sed}$: risk for aquatic organisms
FOE-thiadone	170.1 g/mol		Water/sediment: 84.3% entire system	PECsw/sed risk for aquatic organisms
FOE – methylsulfide	241.33 g/mol		ECsw/sed: >10% of a.s.	PEC sw/sed risk for aquatic organisms

8.3 Rate of degradation in soil (KCP 9.1.1)

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substances.

Evaluation by zRMS	Rate of degradation in soil (KCP 9.1.1)
Comments	No new studies have been submitted regarding degradation in soil for the both of the active susbtances: aclonifen and flufenacet in comparison to the corresponding EU endpoints. DT50 values of aclonifen and flufenacet and its soil relevant metabolites as summarised in this point refer to the results of the EU assessment of these active substances. The formation fractions for both soil metabolites of flufenacet based on data from the DAR were calculated by the applicant appropriate. These values can be used for the calculations of PECgw of flufenacet and its metabolites. Information in this point can be extrapolated to formulation. Therefore no studies have been conducted. EU agreed data were correctly reported.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Aclonifen

The rate of degradation in soil of Aclonifen was evaluated during the Annex I Inclusion. No additional studies have been performed.

The fate and behaviour of Aclonifen in soil is discussed in detail in the corresponding document of the EU review dossier where the study references can be found (EFSA, 2008). A short summary is given below. The degradation of Aclonifen in soil is principally mediated by micro-organisms under aerobic conditions; studies under sterile or anaerobic conditions and the soil surface photolysis study demonstrated that Aclonifen was relatively stable. During the course of the studies, no metabolites have been observed at amounts > 5% of applied radioactivity.

Table 0-1: Summary of aerobic degradation rates for Aclonifen - laboratory studies

Aclonifen, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.°C**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Aldhams House (94/8/2)	Silty sand	6.7	20	60	134	443	93.6	10.4	SFO	Y EFSA, 2008
Shelley Field (94/9/2)	Silty loam	7.0	20	60	73	242	51.0	7.2	SFO	
Westleton (94/10/2)	Silty loam	6.8	20	60	95	315	66.4	5.4	SFO	
Westleton (94/10/2)	Silty sand	6.8	20	30	>>118				Reduced soil moisture	
Arable	Sandy loam	7.3	22	40	32	107	29.5	10.1	SFO	
Standard Soil 2.3	Sandy loam	6.6	22	40	78	259	72.6	4.8	SFO	
Speyer 2.2 A	Loamy sand	6.0	22	40	93	309	83.7	0.7	SFO, initial residue at day 14	
Speyer 2.2 B	Loamy sand	6.0	22	40	76	254	68.7	2.7	SFO, initial residue at day 14	
Speyer 2.3	Sandy loam	7.0	22	40	34 53	114 177	41.9	2	SFO, initial residue at day 14	
Westleton	Loamy sand	6.8	10	50	222	740	86.5	3.4	SFO	
Stockland	Clay loam	7.2	10	50	206 218	684 723	61.8	3.2	SFO	
Geometric mean/Median(n=11)							62.3/67.6			
pH-dependency:							No			

The proposed degradation pathway in soil is presented in Figure 8.3-1.

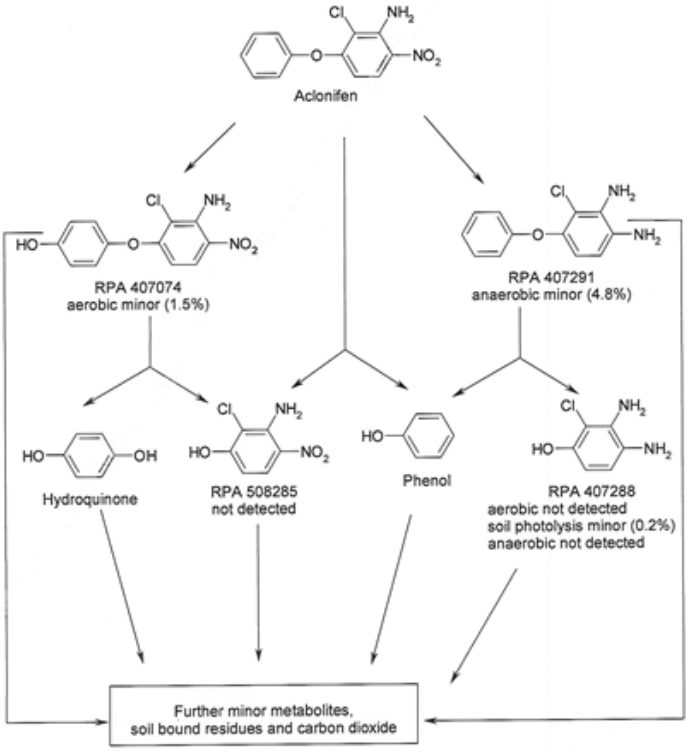


Figure 8.3-1: Proposed metabolic pathway of Aclonifen in soil

8.3.1.2 Flufenacet

The route and rate of degradation in soil of Flufenacet was evaluated during the Annex I Inclusion. No additional studies have been performed. The fate and behaviour of Flufenacet in soil is discussed in detail in the corresponding document of the EU reviews dossiers where the study references can be found. Except for the normalisation of flufenacet data and calculation of formation fractions and transformation rates for flufenacet and its relevant soil metabolites, no further recalculations were performed.

Under aerobic conditions Flufenacet was degraded to the major soil metabolites, FOE sulfonic acid (max. 26.3%) and FOE oxalate (max. 15.6%). Minor metabolites were: FOE alcohol, FOE thiglycolate, sulfoxide, FOE methylsulfoxide, FOE methyl sulfone, FOE chloroacetanilide and thiadone. The mineralization reached 10.2-20.8% (fluorophenyl) and 31.9% (thiadiazole) after 90 days. Bound residues reached 29.9-56.2 % (fluorophenyl) and 6.0% (thiadiazole) after 90 days.

Table 0-2: Summary of aerobic degradation rates for flufenacet - laboratory studies

Reference	Test Soil	Incubation temperature and moisture	DT_{50} not normalised [days]	DT_{50} normalised to 20°C and pF2 [days]
Kelley, I.; Wood, S. & McKinney, M. 1995	BBA 2.2 Loamy sand	20ºC / 40% WHC	31	24
	Laacherhof Silt loam	20ºC / 40% WHC	21	13
	Hofchen Silt loam	20ºC / 40% WHC	23	14
Geometric mean:				16.5

DT50 for the major metabolites FOE sulfonic acid and FOE oxalate were calculated in the DAR addendum using data from the Kelly et a. (1995a) parent study reported in the monograph.

Table 0-3: Summary of aerobic degradation rates for FOE sulfonic acid - laboratory studies

Reference	Test Soil	Incubation temperature and moisture	DT_{50} not normalised [days]	DT_{50} normalised to 20°C and pF2 [days]
Kelley, I.; Wood, S. & McKinney, M. 1995	BBA 2.2 Loamy sand	20ºC / 40% WHC	189	119
	Laacherhof Silt loam	20ºC / 40% WHC	247	123
	Hofchen Silt loam	20ºC / 40% WHC	270	189
Geometric mean				140

Table 0-4: Summary of aerobic degradation rates for FOE oxalate - laboratory studies

Reference	Test Soil	Incubation temperature and moisture	DT_{50} not normalised [days]	DT_{50} normalised to 20°C and pF2 [days]
Kelley, I.; Wood, S. & McKinney, M. 1995	BBA 2.2 Loamy sand	20ºC / 40% WHC	5	4
	Laacherhof Silt loam	20ºC / 40% WHC	17	10
	Hofchen Silt loam	20ºC / 40% WHC	12	7
Geometric mean				6.6

Furthermore, in the DAR addendum the rate constants and DT50 for the metabolites FOE-sulfonic acid and FOE-oxalate were calculated based on the Kelley et al. study from 1995. The applicant calculated the formation fractions for both soil metabolites based on these data from the DAR as is shown in the table below.

Table 0-5: Formation fractions for FOE-sulfonic acid and FOE-oxalate (DAR addendum)

Reference	Test Soil	Transformation rate (k)	DT50 (calculated based on ln2/total transformation rate)	Formation fractions for FOE-sulfonic acid and FOE-oxalate (calculated based on individual transformation rate*DT50/ln2)
Kelley, I.; Wood, S. & McKinney, M. 1995	BBA 2.2 Loamy sand	Total = 0.022223 FOE-sulfonic acid = 0.006762 FOE-oxalate = 0.01158	31.19	FOE-sulfonic acid = 0.3043 FOE-oxalate = 0.5211
	Laacherhof Silt loam	Total = 0.0331491 FOE-sulfonic acid = 0.009667 FOE-oxalate = 0.01563	20.91	FOE-sulfonic acid = 0.2916 FOE-oxalate = 0.47151
	Hofchen Silt loam	Total = 0.030683 FOE-sulfonic acid = 0.005565 FOE-oxalate = 0.01287	22.59	FOE-sulfonic acid = 0.1814 FOE-oxalate = 0.4194
Geometric mean				FOE-sulfonic acid = 0.252 FOE-oxalate = 0.469

Subsequently, the rate constant (k) for transformation of the active substance flufenacet into both metabolites, FOE-sulfonic acid and FOE-oxalate, is calculated by the applicant based on the geomean normalised DT50 and the above calculated geomean formation fraction (ff) of both metabolites:

$k_{FOE\text{-}sulfonic\ acid} = ln2/DT_{50} * ff_{FOE\text{-}sulfonic\ acid}$
$= ln2/19.99 * 0.252$
$= 0.00874$

$k_{FOE\text{-}oxalate} = ln2/DT_{50} * ff_{FOE\text{-}oxalate}$
$= ln2/19.99 * 0.469$
$= 0.01626$

It is considered that flufenacet forms FOE-sulfonic acid and FOE-oxalate and that the remaining part of the active substance is converted into CO2. Consequently, the formation fraction for flufenacet into CO2 equals:

$1 – 0.252 – 0.469 = 0.279$

And thus the transformation rate for the conversion of flufenacet into CO_2

$= ln2/19.99 * 0.279$
$= 0.00967$

The above calculated formation fractions and rate constants will be used for the calculations of PECgw of flufenacet and its metabolites.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Studies on anaerobic degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.3.2.1 Aclonifen

The DT50 value for the degradation of Aclonifen in soil incubated at 22 °C under anaerobic conditions was 6 days in Speyer 2.3 soil, assuming first order kinetics. The degradation rate under anaerobic conditions was significantly faster than the rate observed under aerobic conditions.

8.3.2.2 Flufenacet

No data was provided during the Annex Review of flufenacet as it was not required. It was considered that, due to the use patterns (application as pre-or early-post emergence herbicide in maize and cereals) it can be justified that flufenacet will not be exposed to anaerobic conditions. Therefore, a study on anaerobic degradation was not required.

8.4 Field studies (KCP 9.1.1.2)

Field studies with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substances.

Evaluation by zRMS	**Field studies (KCP 9.1.1.2)**
Comments	No new data. Information in Section 8.4 is available in dossier of active substances: aclonifen and flufenacet and can be extrapolated to formulation. Therefore no studies have been conducted.

8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

8.4.1.1 Aclonifen

Studies on field dissipation in soil of Aclonifen have been reviewed during the EU Review of the active substance. No additional studies have been performed. The information regarding the EU endpoints, calculated from the field studies, for Aclonifen are presented in the table below.

Triggering endpoints

Field dissipation studies for the use of Aclonifen were part of the EU review on Aclonifen and are summarised in the EFSA Scientific Report (2008) 149, 1-80. Results from the field dissipation studies on Aclonifen are given in Table 8.4-1.

Table 0-1: Summary of aerobic degradation rates for Aclonifen - field studies: Triggering endpoints

Aclonifen, Field studies – Triggering endpoints									
Location	**Soil type**	**pH**	**Depth (cm)**	**DissT50 (d) actual**	**DT90 (d) actual**	**DT50 (d) 20°C pF2/10kPa**	**Chi² (%)**	**Method of calculation**	**Evaluated on EU level**
Goch-Nierswalde, Germany	Silty loam	5.9	0-10	61	202	-	13.3	SFO	Y EFSA, 2008
Meißner-Vockerode, Germany	Silty loam	6.4	0-10	119	395	-	25.9	SFO	
Schwichteler, Germany	Sandy loam	6.3	0-30	195	649	-	11.3	SFO	

Aclonifen, Field studies – Triggering endpoints									
Location	**Soil type**	**pH**	**Depth (cm)**	**DissT50 (d) actual**	**DT90 (d) actual**	**DT50 (d) 20°C pF2/10kPa**	**Chi² (%)**	**Method of calculation**	**Evaluated on EU level**
Niederkirchen, Germany	Sandy loam	7.3	0-30	13/57[1]	188.7	-	7.2	FOMC (α = 0.72, β = 8.29)	
Almacelles, Spain	Clay loam (cropped with sunflower)	7.8	0-30	51/108[1]	357	-	18.1	FOMC (α = 1.279, β = 70.628)	
Cruas, France (Southern EU)	Sandy silt loam	5.9	0-30	31	104	-	14.7	SFO	
Maximum (n=6)				195	649				

[1] first order DT_{50} ($DT_{50} = DT_{90}/3.32$ see FOCUS Degradation Kinetics)

Modelling endpoints

For modelling of the $PEC_{groundwater}$ and $PEC_{surface\ water}$ of Aclonifen, the geometric mean DT_{50} of the laboratory trials of 62.3 days is used. For calculation of the PEC_{soil}, the longest DT_{50} value of the field trials of 195 days is used.

8.4.1.2 Flufenacet

The rate of degradation in soil of flufenacet in field studies was evaluated during the Annex I Inclusion. No additional studies have been performed. The agreed EU endpoints are presented below. Results from the field dissipation studies on flufenacet showed the DT50 to range from 13 to 53. More details can be found in the EU review report and DAR plus DAR addendum.

DT50 from soil dissipation studies	DT50 Germany (4 sites, bare soil), Northern France (2 sites, crop), Southern France (2 sites, crop), Italy (2 sites, crop). LOD 10µg/kg (<6%)			
	Location	Autumn	Early Spring	Spring
		(240 g/ha)	(240 g/ha)	(480-600 g/ha)
	Germany	38-43d	-	15.54-31.53d
	N-France	-	13-16d	16-38d
	S-France	-	-	30-36, 34-42d
	Italy	-	-	38-48d
	Metabolites not detected above LOD			
ST90 from soil dissipation studies	DT90: same conditions as for DT50			
	Location	Autumn	Early Spring	Spring
		(240 g/ha)	(240 g/ha)	(480-600 g/ha)
	Germany	125-144d	-	51-178-101-177d
	N-France	-	43-52d	177-198d
	S-France	-	-	98-120-112-139d
	Italy	-	-	126-158d

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

8.4.2.1 Aclonifen

The accumulation of aclonifen was evaluated for the approval of the active substance (please refer to the EFSA scientific report 2008). No additional studies have been performed

rep.

8.4.2.2 Flufenacet

No data, not required since flufenacet is not persistent in soil (DT90 < 365 days). Potential accumulation of its metabolite FOE sulfonic acid is addressed by calculation under Section 8.7.

8.5 Mobility in soil (KCP 9.1.2)

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

Evaluation by zRMS	**Field studies (KCP 9.1.2)**
Comments	No new data. Information in Section 8.5 is available in dossier of active substances: aclonifen and flufenacet and can be extrapolated to formulation. Therefore no studies have been conducted. EU agreed data were correctly reported.

Aclonifen
Studies on mobility in soil of Aclonifen have been reviewed during the EU Review of the active substance. The mobility in soil of Aclonifen was evaluated during the Annex I Inclusion. No additional studies have been performed.

A summary of the available studies on adsorption/desorption of Aclonifen is given in Table 8.5-1. The adsorption of Aclonifen was not dependent on soil pH but was correlated with soil organic carbon. Standard adsorption/desorption studies indicated that Aclonifen is immobile in soil. The K_{oc} values obtained ranged from 5318 to 10612 (mean value 7126).

Table 0-1: Summary of soil adsorption/desorption for Aclonifen

Aclonifen							
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
90/8, Chazay d'Azergues, France	Loam	1.1	6.4	58.5	5318	0.878	Y EFSA, 2008
90/10, nr Milland, West Sussex, England, UK	Sandy loam	1.7	7.3	92.6	5447	0.885	
90/9 Speyer 2.2, Speyer, Germany	Loamy sand	2.5	5.7	265.3	10612	1.003	

Aclonifen							
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Arithmetic mean (n=3)					7126	0.922	
pH-dependency y/n					No		

Flufenacet

The mobility in soil of flufenacet and its metabolites was evaluated during the Annex I Inclusion. No additional studies have been performed.

A summary of the available studies on adsorption/desorption of flufenacet in soil is given in the table below. Koc values are available from 7 and 4 studies for the active substance and metabolites respectively. However, the mean Koc value and 1/n were based on the values originating from soils with an organic content higher than 0.23% for the active substance and higher than 0.27% for the metabolites.

Based on these data and as was concluded during the EU review of flufenacet, the sorption of flufenacet is not pH dependant.

Table 0-2: Summary of soil adsorption/desorption for Flufenacet

Soil name	**Soil type**	**OC (%)**	**pH (-)**	**Koc (mL/g)**	**Slope (-)**	**Evaluated on EU level y/n/ Reference**
Silt loam	Silt loam	1.68	5.9	190	0.84	Y EC Review Report 2003
Clay Loam	Clay Loam	1.28	6.4	211	0.90	
Loamy sand	Loamy sand	0.23	6.4	696	0.87	
Sand	Sand	0.17	5.0	588	0.98	
Sandy loam	Sandy loam	1.4	6.4	354	0.89	
Loam	Loam	4.3	7.1	113	0.96	
Silt loam	Silt loam	2.8	7.3	144	0.86	
Arithmetic mean (soils with OC> 0.23%)				202	0.980	
pH-dependency y/n					No	

Table 0-3: Summary of soil adsorption/desorption for FOE-oxalate

Soil name	**Soil type**	**OC (%)**	**pH (-)**	**Kfoc (mL/g)**	**Slope (-)**	**Evaluated on EU level y/n/ Reference**
Sand	Sand	0.27	5.8	23	1.42	Y EC Review Report 2003
Sandy loam	Sandy loam	0.75	6.3	13	0.93	
Silty clay loam	Silty clay loam	2.13	6.6	7	0.82	
Silty clay	Silty clay	1.21	6.0	13	0.98	

Soil name	Soil type	OC (%)	pH (-)	Kfoc (mL/g)	Slope (-)	Evaluated on EU level y/n/ Reference
Arithmetic mean (soils with OC> 0.23%)				11	0.910	
pH-dependency y/n					no	

Table 0-4: Summary of soil adsorption/desorption for FOE-sulfonic acid

Soil name	Soil type	OC (%)	pH (-)	Kfoc (mL/g)	Slope (-)	Evaluated on EU level y/n/ Reference
Sand	Sand	0.27	5.8	19	0.86	Y EC Review Report 2003
Sandy loam	Sandy loam	0.75	6.3	15	1.00	
Silty clay loam	Silty clay loam	2.13	6.6	10	0.93	
Silty clay	Silty clay	1.21	6.0	6	1.18	
Arithmetic mean (soils with OC> 0.23%)				10	1.040	
pH-dependency y/n					no	

8.5.1 Column leaching (KCP 9.1.2.1)

Aclonifen

Soil column leaching studies conducted with Aclonifen and aged residues of Aclonifen were submitted during the EU review. The results of these studies support the conclusion of the adsorption/desorption tests, namely that aclonifen is practically immobile in soil (EFSA, 2008).

Flufenacet

Aged column leaching studies for flufenacet were evaluated for the approval of the active substance, please refer to the Review Report 2003. No additional studies have been performed.

Flufenacet was aged for 30 and 90 days in soils (pH 6-6.2, OC 0.26-0.32%). Details on radioactivity in leachates (%) are presented in Table 8.5.1-5

Table 8.5-5: Summary of behaviour in soil (Review Report 7469/VI/98 – 03 July 2003)

Substance	Results % applied radioactivity in the leachate	
	30 days	90 days
Total	<30%	<44%
Parent	<16%	<0.3%
FOE oxalate (M1)	<6.7%	<27%
FOE sulfonic acid (M2)	<10.1%	<10.9%
FOE thioglycolate sulfoxide (M4)	<6.2%	<3.6%
Others	<1.6%	<2.9%

Based on these results it can be concluded that flufenacet and its metabolites may be leached into deeper soil layers. However, with regard to their quantitative significance, only flufenacet itself, as well as FOE sulfonic acid and FOE oxalate may be expected to appear in relevant amounts.

Column leaching and aged soil column leaching studies showed 0.01 to 0.9% of the applied substance in the leachates, respectively (EFSA, 2010).

8.5.2 Lysimeter studies (KCP 9.1.2.2)

Aclonifen

Since Aclonifen is immobile in soil as confirmed by the adsorption/desorption and column leaching studies, lysimeter studies are not formally required and were therefore not performed.

Flufenacet

Two lysimeter studies were conducted with Flufenacet taken into account different crop rotations (maize/maize rotation, maize/wheat rotation) and repeated applications of the active ingredient.
Results are summarised in the Table below.

Table 8.5-6: Summary of behaviour in soil (Review Report 7469/VI/98 – 03 July 2003)

Test system	Results
2 appln./year at 480 g a.s./ha	Total residue of three year: 0.23-2.23 µg/L a.s. < 0.035 µg/L FOE oxalate <0.04 µg/L FOE thiglycolate <0.008 µg/L FOE sulfonic acid 0.15-1.29 µg/L
2 appln./year at 480+180 g a.s./ha	Total residue of two year: 0.24-5 µg/L a.s. No identified FOE oxalate and FOE thiglycolate <0.1 µg/L FOE sulfonic acid 0.015-3.7 µg/L

8.5.3 Field leaching studies (KCP 9.1.2.3)

Aclonifen

Since Aclonifen is immobile in soil as confirmed by the adsorption/desorption and column leaching studies, field leaching studies are not formally required and were therefore not performed.

Flufenacet

No data were required, since the risk of leaching to groundwater is low.

8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substances.

Evaluation by zRMS	Degradation in the water/sediment systems (KCP 9.2)
Comments	No new data. Information in Section 8.6 is available in dossier of active substances: aclonifen and flufenacet and can be extrapolated to formulation. Therefore no studies have been conducted. EU agreed data were correctly reported.

8.6.1 Aclonifen

Studies on degradation in water/sediment systems of Aclonifen have been reviewed during the EU Review of the active substance. The fate and behaviour of Aclonifen in surface water has been investigated under abiotic and biotic conditions. Under sterile aqueous conditions, at temperatures of 22 °C, 50 °C and 70 °C, Aclonifen was found to be hydrolytically stable at pH 5, 7 and 9.

The photolytic degradation of Aclonifen in water has been investigated under sterile conditions in phosphate buffer solution at pH 7. Aclonifen exhibited slow degradation when irradiated in sterile pH 7 buffer solution at 25 °C, with up to 88 % of applied radioactivity still recovered as parent at the end of the study after 16 days (equivalent to 30 days natural sunlight). No major (> 10 %) metabolites were formed by photolysis in water.

Aclonifen was found to be not readily biodegradable under the stringent conditions of OECD guideline 301B in which only very limited opportunity for biodegradation and microbial acclimatisation was provided.

In water/sediment systems, Aclonifen was rapidly degraded with overall DT_{50} values ranging from 9.1 to 11 days. The compound dissipated rapidly from the water phase with DT_{50} values of between 1.6 and 3 days. The formation of unextractable bound residues in the sediment was found to be a major elimination process, with degradation of Aclonifen to a number of minor metabolites also observed in water and sediment. Aclonifen was degraded by hydroxylation to form RPA 407074 and hydrolysis (of Aclonifen or RPA 407074) to form RPA 508285. Under reduced conditions, the formation of RPA 407288 was observed occasionally, possibly as a result of the reduction of RPA 508285 as the reduced forms of Aclonifen and RPA 407074 were not observed. No major metabolites were observed in either the water or the sediment phase. Cleavage of the diphenyl ether linkage would result in the formation of phenol and hydroquinone in addition to RPA 508285 and RPA 407288. The combined sum of cleaved metabolites observed throughout the water sediment study was at a maximum of only 4 %. The fate and behaviour of phenol and hydroquinone has been evaluated and confirms they are both readily metabolised in aquatic systems.

Table 0-1: Summary of degradation in water/sediment of Aclonifen

Aclonifen Distribution (max. water/sediment 5/89 % after 180 days)										
Water/ sediment system	**pH water/ sed.**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**Kinetic, Fit**	**Diss T50 water (d)**	**Diss T90 water (d)**	**Kinetic, Fit**	**Diss T50 sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Manningtree (sandy silt loam)	6.7/6.8	11.2	37.9	SFO (non-linear) Chi² 18.5	3.2	-	SFO (non-linear)	92	SFO (non-linear)	Y DE, 2006 DE, 2008 EFSA, 2008
Ongar (clay loam)	7.5/8.4	37.9	57.7	SFO (non-	5.6	-	SFO (non-	No decline	SFO (non-	

Aclonifen Distribution (max. water/sediment 5/89 % after 180 days)										
Water/ sediment system	**pH water/ sed.**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**Kinetic, Fit**	**Diss T50 water (d)**	**Diss T90 water (d)**	**Kinetic, Fit**	**Diss T50 sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
				linear) Chi² 13.4			linear)		linear)	
Geometric mean (n=2)		-	-		4.2/ 4.4[1)]	-		1000 *[1)]		

* 1000 d worst-case assumption; [1)] For PECsw and PECsed calculations, separated DT_{50} for water and sediment cannot be used, instead worst-case $DT_{50\ whole\ syst.}$ of 17.3 d to be used.

8.6.2 Flufenacet and its metabolites

The degradation of flufenacet in water/sediment systems was evaluated for the approval of the active substance, please refer to the Review Report 2003. No additional studies have been performed.

Table 0-2: Summary of degradation in water/sediment of Flufenacet

Type of study	Matrix	Concentration (mg a.i./L)	Temp (°C)	Light source	Half-live 1st order	Remarks
Hydrolysis	pH5 : 0.01 M acetate buffer pH7 : 0.01 M phosphate buffer pH9 : 0.01 M borate buffer	10	25	dark	pH5 : > 1 year pH7 : >1 year pH9 : >1 year	N degradation products detected
Photolysis	0.01 M sodium acetate buffer (pH5) + 1% acetonitrile	1	25	Xenon-arc lamps	>1 year	No photolysis products detected. Environmental DT50 >>1 year
Indirect photolysis	a) pond water b) pond water c) pure water + humic acid d) pure water + KNO3	1	25	Xenon-arc lamps	a) 148d b) 473d c) 148d d) 32d	Environmenal DT50: a) 433d b) >>1year c) 433d d) 95d
Quantum yield	Water/acetonitrile (9:1)	5.6	25	TQ high pressure Hg-lamp with Duran 50 filter	a) 179 hours b) 374 hours	Quantum yield: 0.00096 Environmental DT50: 126d to >1 year
Biological degradation	Water/sediment: a) NESA b) BRP	0.27-0.28	20	Dark	a) 61.7 d b) 46.3 d	M1, M2, M3, M4, M5, M6, M7 detected but not in significant amounts

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	pH 5 (25° C) DT_{50} > 1 year
	pH 7 (25° C) DT_{50} > 1 year
	pH 9 (25° C) DT_{50} > 1 year
Photolytic degradation of active substance and relevant metabolites	Not significant (DT_{50} > 1 year)
Readily biodegradable (yes/no)	No data
Degradation in water/sediment - DT_{50} water - DT_{90} water	46.3 - 61.7 d (fluoropheny, 1st order) 154 - 205 d
- DT_{50} whole system - DT_{90} whole system	76.4 - 84.6 d (fluorophenyl), 20 - 31 d (thiadiazole) 254 - 281 d (fluorophenyl), 67 - 104 d (thiadiazole)
Mineralization	max. 3.4 % (157 d) for the fluorophenyl moiety max. 15 % (156 d) for the thiadiazole moiety
Non-extractable residues	max. 46.4 % (157 d) for the fluorophenyl moiety < 10 % for the thiadiazole moiety
Distribution in water / sediment systems (active substance)	max. 34.2 % in sediment (30 d)
Distribution in water / sediment systems (metabolites)	FOE methylsulfide max. 8 % in water and 3.4 % in sediment (157 d) Thiadone max. 82 % in water (55 d)

Table 0-3: Modelling endpoints for degradation in water/sediment of flufenacet

End-Point	Flufenacet
Molecular weight [g mol^{-1}]	363.3
Water solubility [mg L^{-1}]	56 (20°C)
DT50 soil [days]	16.5 days
Kfoc arithmetic mean (mL/g)	202.4 (n=5)
1/n arithmetic mean	0.89 (n=5)
pH dependence, Yes or No	No
Maximum occurrence in soil [%] source -> sink relation [-]	100
Water/sediment DT_{50} (d)	44.7 (n=4)
Water DT_{50} (d)	44.7 (n=4)
Sediment DT_{50} (d)	1000
Maximum occurrence in water/sediment [%] source -> sink relation [-]	100

8.7 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

Evaluation by zRMS	**PECsoil (KCP 9.1.3)**
Modelling	The assumptions and results of calculations are acceptable. The predicted environmental concentrations in soil (PECsoil) of aclonifen and flufenacet were calculated according to recommendations of the FOCUS workgroup on degradation kinetics using single application for two application rates on winter cereals: - 1.5l product/ha (810 g/ha aclonifen and 90g/ha flufenacet) - 2.0l product/ha (1080 g/ha aclonifen and 120g/ha flufenacet) For both metabolites of flufenacet the predicted environmental concentrations in soil (PECsoil) were calculated using single application for the max application rate on winter cereals: 2.0l product/ha No interception was considered. It was assumed that the avtive substances were distributed in the top 5 cm soil layer with a soil bulk density of 1.5 g/mL. The calculated PECs values are presented in Tables from 8.7-3 to 8.7-8. The applicant also correctly calculated the PECsoil for the formulation GLOB1310aH. The results are shown in the Table 8.7-9 The calculated PECsoil values for GLOB1310aH, aclonifen and flufenacet as well as its both metabolites are appropriate to be used for the subsequent risk assessment for soil organisms.
Agreed Endpoints	**Aclonifen:** <u>Application rate : 1.5l GLOB1310aH /ha</u> Initial PEC_{soil}: 1.08 mg/kg $PEC_{accumulation}$ = 1.486 mg/kg Plateau concentration = 0.406 mg/kg <u>Application rate : 2.0l GLOB1310aH /ha</u> Initial PEC_{soil}: 1.44 mg/kg $PEC_{accumulation}$ = 1.981 mg/kg Plateau concentration = 0.541 mg/kg **Flufenacet:** <u>Application rate : 1.5l GLOB1310aH /ha</u> Initial PEC_{soil}: 0.12 mg/kg <u>Application rate : 2.0l GLOB1310aH /ha</u> Initial PEC_{soil}: 0.16 mg/kg **Metabolites of flufenacet:** **FOE-sulfonic acid (M2)** **<u>Application rate : 2.0l GLOB1310aH /ha</u>** Initial PECsoil: 0.0319 mg/kg PECaccumulation = 0.0524 mg/kg Plateau concentration = 0.0205mg/kg **FOE-oxalate (M1)** **<u>Application rate : 2.0l GLOB1310aH /ha</u>**

	Initial PECsoil: 0.0319 mg/kg PECaccumulation = 0.0524 mg/kg Plateau concentration = 0.0205mg/kg **Formulation: GLOB1310aH** **Application rate : 1.5l GLOB1310aH /ha** PECact = 3.2752 mg/kg **Application rate : 2.0l GLOB1310aH /ha** PECact = 2.4564 mg/kg

8.7.1 Justification for new endpoints

8.7.2 Active substance(s) and relevant metabolite(s)

Table 0-1: Input parameters related to application for PEC_{soil} calculations

Use No.	1-6	7-14
Crop	Winter cereals	Winter cereals
Growth stage	BBCH 00-09	BBCH 00-09
Application rate (g as/ha)	Aclonifen: 810 Flufenacet: 90	Aclonifen: 1080 Flufenacet: 120
Number of applications/interval	1/-	1/-
Crop interception (%)	0	0
Depth of soil layer (relevant for plateau concentration) (cm)	5/20cm (no tillage/tillage)	5/20cm (no tillage/tillage)

It is considered that the PECsoil simulation of Use 2 cover the other requested uses.
The PEC_{soil} calculations were performed for a standard soil considering a dry soil bulk density of 1.5 g/cm^3 and 5 cm soil depth in agreement with the recommendation of the EU guideline FOCUS (1997) [1]. No interception was considered (pre-emergence and early post-mergence application application).

In case of persistent substances in soil, PEC plateau and PEC accumulation have to be calculated. Aclonifen and the flufenacet metabolite FOE-sulfonic acid are both candidate to soil accumulation.

The Plateau maximum PECs were calculated (in accordance with the SANCO 7617 VI 96) to account for the accumulation by means of the following equations:

[1] FOCUS (1997) Soil persistence models and EU Registration - The Final Report of the Soil Modelling Workgroup of FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use) – 29 February 1997.

Plateau average PEC_s = Initial PEC_s for 1 application / ki

Plateau maximum PEC_s = Initial PEC_s for 1 application / (1 - e^{-ki})

where k = ln 2 / DT_{50} = ln 2 / DT_{50}

i = interval between the applications = 365

The PEC accumulation is the sum of the initial PEC (5cm) and the PEC plateau (20cm).

A summary of the input parameters for each active ingredient is given in table 8.7-2 below

Table 0-2: Input parameter for active substances and relevant metabolites for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
Aclonifen (active substance)	264.7	-	195d (SFO kinetics, max field studes)	Y, EFSA Report 2008
Flufenacet (active susbtance)	363.3	-	54d (max. field, not normalized)	Y, Review Report 7469/VI/98 Final, July 2003
FOE-sulfonic acid (M2)	275.3	26.3	270 d (max, laboratory study)	Y, Review Report 7469/VI/98 Final, July 2003
FOE-oxalate (M1)	225.2	15.6	17 d (max;, laboratory study)	Y, Review Report 7469/VI/98 Final, July 2003

8.7.2.1 Aclonifen and its metabolites

Table 0-3: PEC_{soil} for Aclonifen on winter cereals

PEC_{soil} (mg/kg)		Winter cereals	
		Single application (2L GLOB1310aH/ha)	
		Actual	TWA
Initial		1.4400	-
Short term	24h	1.4349	1.4374
	2d	1.4298	1.4349
	4d	1.4197	1.4298
Long term	7d	1.4046	1.4222
	14d	1.3701	1.4048
	21d	1.3364	1.3876
	28d	1.3036	1.3707
	50d	1.2055	1.3193
	100d	1.0092	1.2119

Plateau concentration (5 cm)	0.541	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)	1.981	-

Table 0-4: PEC_{soil} for Aclonifen on winter cereals

PEC_{soil} (mg/kg)		Winter cereals	
		Single application (1.5L GLOB1310aH/ha)	
		Actual	TWA
Initial		1.080	-
Short term	24h	1.076	1.078
	2d	1.072	1.076
	4d	1.065	1.072
Long term	7d	1.053	1.067
	14d	1.028	1.054
	21d	1.002	1.041
	28d	0.978	1.028
	50d	0.911	0.993
	100d	0.757	0.909
Plateau concentration (5 cm)		0.406	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		1.486	-

8.7.2.2 Flufenacet and its metabolites

Table 0-5: PEC_{soil} for Flufenacet on winter cereals

PEC_{soil} (mg/kg)		Winter cereals (120 g Flufenacet/ha, pre-emergence)	
		Single application	
		Actual	TWA
Initial		0.1600	-
Short term	24h	0.1580	0.1590
	2d	0.1559	0.1580
	4d	0.1520	0.1560
Long term	7d	0.1463	0.1530
	14d	0.1337	0.1464
	21d	0.1222	0.1402
	28d	0.1117	0.1344
	50d	0.0842	0.1181
	100d	0.0443	0.0901

Plateau concentration (5/20 cm)	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)	-	-

Table 0-6: PEC_{soil} for Flufenacet on winter cereals

PEC_{soil} (mg/kg)		Winter cereals (90 g Flufenacet/ha, pre-emergence)	
		Single application	
		Actual	TWA
Initial		0.120	-
Short term	24h	0.118	0.119
	2d	0.117	0.118
	4d	0.114	0.117
Long term	7d	0.110	0.115
	14d	0.100	0.110
	21d	0.092	0.105
	28d	0.084	0.101
	50d	0.065	0.090
	100d	0.033	0.068
Plateau concentration (5/20 cm)		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

PEC_{soil} of metabolites

Table 0-7: PEC_{soil} for FOE-sulfonic acid (M2) on winter cereals

PEC_{soil} (mg/kg)		Winter cereals (2.0L formulation/ha, pre-emergence)	
		Single application	
		Actual	TWA
Initial		0.0319	-
Short term	24h	0.0318	0.0318
	2d	0.0317	0.0318
	4d	0.0316	0.0317
Long term	7d	0.0313	0.0316
	14d	0.0308	0.0313
	21d	0.0302	0.0310
	28d	0.0297	0.0308
	50d	0.0280	0.0299
	100d	0.0247	0.0281
Plateau concentration		0.0205	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$) no tillage		0.0524	-

Table 0-8: PEC_{soil} for FOE-oxalate (M1) on winter cereals

PEC_{soil} (mg/kg)		Winter cereals (2.0L formulation/ha, pre-emergence)	
		Single application	
		Actual	TWA
Initial		0.0155	-
Short term	24h	0.0149	0.0152
	2d	0.0143	0.0149
	4d	0.0131	0.0143
Long term	7d	0.0116	0.0135
	14d	0.0087	0.0118
	21d	0.0066	0.0104
	28d	0.0049	0.0092
	50d	0.0020	0.0066
	100d	0.0003	0.0037
Plateau concentration (5/20 cm)		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

8.7.2.3 PEC_{soil} of GLOB1310aH

Table 0-9: PEC_{soil} for GLOB1310aH on winter cereals

Active substance/ reparation	**Application rate (g/ha)**	**PEC_{act} (mg/kg)**	**PEC_{twa}21 d (mg/kg)**	**Tillage depth (cm)**	**$PEC_{soil,plateau}$ (mg/kg)**	**PEC_{accu} = PEC_{act} + $PEC_{soil,plateau}$ (mg/kg)**
GLOB1310aH	2456.4g (2L formulation/ha)*	3.2752	-	-	-	-
	1842.3g (1.5L formulation/ha)*	~~2.4654~~ 2.4564	-	-	-	-

*based on a formulation density of 1.2282 g/mL

8.8 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

Evaluation by zRMS	**PECgw (KCP 9.2.4)**
Modelling	For the active substances aclonifen and flufenacet as well as for both metabolites of flufenacet the calculations presented here are accepted. The applicant has used appropriate models for ground water FOCUS-PEARL 4.4.4 FOCUS-PELMO 5.5.3. PEC_{GW} values were calculated for single applica-

	tion using two application rate 1.5l formulation/ha pre-emergence and 2l formulation/ha pre-emergence on winter cereals. For flufenacet and its metabolites PECgw calculations were made also in the Tier 2. Input parameters used in FOCUS ground water modelling for active substances and two metabolites of flufenacet are correct.
PECgw	Results of modelling with FOCUS PELMO 5.5.3 and PEARL 4.4.4 show that the active substances aclonifen and flufenacet are not expected to penetrate into groundwater at concentrations of ≥ 0.1 µg/L in any of the intended uses for all scenarios. Results of the modelling with FOCUS PELMO 5.5.3 and PEARL 4.4.4 show that the metabolite of flufenacet: FOE oxalate (M1) exceed 0.1 µg/L in some scenarios (max. 0.140159 µg/L, for use of 2L GLOB1310aH/ha at pre-emergence in Okehampton scenario) based on Tier 2 FOCUS PEARL. However, using FOCUS PELMO model in the Tier 2 PECgw for FOE oxalate (M1) are below 0.1 µg/L in all scenarios. In the case of the second metabolite of flufenacet: FOE sulfonic acid (M2) PECgw exceed 0.1 µg/L in all scenarios, except Sevilla, (max. value:2.724940 µg/L, for use of 2L GLOB1310aH/ha at pre-emergence in Joikionen scenario). Additionally, using FOCUS PELMO model in the Tier 2 the PECgw for FOE sulfonic acid (M2) exceed 0.1 µg/L in all scenarios. The max. value: 2.682 µg/L, for use of 2L GLOB1310aH/ha at pre-emergence calculated in Joikionen scenario.
Conclusion for risk assessment	An assessment of metabolites of flufenacet regarding their relevance for groundwater is necessary. For the assessment of relevance please refer to Part B, Section 10.

8.8.1 Justification for new endpoints

Deviations from the EU agreed endpoints were made and are explained in the table 8.8-2.

Additionally, in the Tier 2 modelling for Flufenacet, PECgw calculations were performed based on the following refinement: a DT50 value of 21.7 days (geometric mean) was used as input parameter for FOE-sulfonic acid. This DT50 value for FOE-sulfonic acid originates from a study from the notifier from the Annex I inclusion of flufenacet in which a kinetic re-evaluation of the data from the field dissipation studies from the DAR of flufenacet is performed. As it concerns a re-evaluation of existing unprotected data and not new data, this study is therefore not protected and the DT50 value of 21.7 from this study can thus be used in support of GLOB1310aH.

8.8.2 Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1)

Table 0-1: Input parameters related to application for PEC_{gw} calculations

Use No.	1	3
Crop	Winter cereals	Winter cereals
Growth stage	BBCH 00-09	BBCH 00-09
Application rate (g as/ha)	Aclonifen: 810 Flufenacet: 90	Aclonifen: 1080 Flufenacet: 120
Number of	1/-	1/-

applications/interval (d)		
Relative application date	7 days before emergence	7 days before emergence
Crop interception (%)	0%	0%
Frequency of application	annual	annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3,	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3,

8.8.2.1 Aclonifen

FOCUS PEARL Tier 1 PECgw

Table 0-2: Input parameters related to active substance Aclonifen for PEC_{gw} calculations

Compound	Aclonifen	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	264.7	Y, EFSA 2008
Water solubility (g/mol):	T1: 1.4 (20°C) T2: 2.8 (30°C)	Y, EFSA 2008 2x to pass from T1 to T2
Saturated vapour pressure (Pa):	T1: $1.6 * 10^{-5}$ (20°C) T2: $6.4 * 10^{-5}$ (30°C)	Y, EFSA 2008 4x to pass from T1 to T2
DT_{50} in soil (d)	Geomean: 62.3	Y, EFSA 2008
Transformation rate	0.011126	Y, EFSA 2008
K_{foc} (mL/g)/K_{fom}	Kfoc: 5318	Worst case
1/n	0.878	Y, EFSA 2008
Plant uptake factor	0	Y, EFSA 2008
Formation fraction	-	Y, EFSA 2008

Table 0-3: PEC_{gw} for Aclonifen on winter cereals (with FOCUS PEARL 4.4.4 Tier 1) use 1-6 (1.5L/ha GLOB1310aH pre-emergence)

Crop	Scenario	80^{th} Percentile PEC_{gw} at 1 m Soil Depth (µg/L)
		Aclonifen
Winter cereals	Châteaudun	0.000000
	Hamburg	0.000000
	Jokioinen	0.000000
	Kremsmünster	0.000000
	Okehampton	0.000000

	Piacenza	0.000000
	Porto	0.000000
	Sevilla	0.000000
	Thiva	0.000000

Table 0-4: PEC_{gw} for Aclonifen on winter cereals (with FOCUS PEARL 4.4.4 Tier 1) use 7-12 (2L/ha GLOB1310aH pre-emergence)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)
		Aclonifen
Winter cereals	Châteaudun	0.000000
	Hamburg	0.000000
	Jokioinen	0.000000
	Kremsmünster	0.000000
	Okehampton	0.000000
	Piacenza	0.000000
	Porto	0.000000
	Sevilla	0.000000
	Thiva	0.000000

Based on Tier 12 FOCUS PEARL:

- PECgw for Aclonifen are below 0.1 µg/L in all scenarios

FOCUS PELMO Tier 1 PECgw

Table 0-5: PEC_{gw} for Aclonifen on winter cereals (with FOCUS PELMO 5.5.3 Tier 1) uses 1-6 (1.5L/ha GLOB1310aH pre-emergence)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)
		Aclonifen
Winter cereals	Châteaudun	0.000
	Hamburg	0.000
	Jokioinen	0.000
	Kremsmünster	0.000
	Okehampton	0.000
	Piacenza	0.000
	Porto	0.000
	Sevilla	0.000
	Thiva	0.000

Table 0-6: PEC_{gw} for Aclonifen on winter cereals (with FOCUS PELMO 5.5.3 Tier 1) uses 7-12 (2L/ha GLOB1310aH pre-emergence)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)
		Aclonifen
Winter cereals	Châteaudun	0.000
	Hamburg	0.000
	Jokioinen	0.000
	Kremsmünster	0.000
	Okehampton	0.000
	Piacenza	0.000
	Porto	0.000
	Sevilla	0.000
	Thiva	0.000

Based on Tier 12 FOCUS PELMO:

- PECgw for Aclonifen are below 0.1 µg/L in all scenarios

8.8.2.2 Flufenacet and its metabolites

Table 0-7: Input parameters related to active substance Flufenacet and metabolites for PEC_{gw} calculations

Compound	Flufenacet	FOE-sulfonic acid (M2)	FOE-oxalate (M1)	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	363.3	275.3	225.2	Y, LoEP flufenacet
Water solubility (g/mol):	56 (20°C) 112 (30°C)	1000	1000	Since no solubility values are available for both metabolites in Review Report 2003, the default value is used Solubility at 30° for the active substance was calculated as: Solubility at (T1+10°C) = 2 x Solubility at T1, being T1 20°C
Saturated vapour pressure (Pa):	$9x10^{-5}$ (20°C) $36x10^{-5}$ (30°C)	$1x10^{-10}$	$1x10^{-10}$	Default values used for the metabolites Vapour pressure at 30°C for the active substance was calculated as: Vapour pressure at (T1 +10°C) = 4 x Vapour pressure at T1, bein T1 20°C
DT_{50} in soil (d)	16.5	Tier 1: 140 (n=3), geometric mean lab values normalized to 20°C Tier 2**: 21.7 (n=11, geomean, field normalisation to pF2 20°C with Q10 of 2.2)	6.6 (n=3), geometric mean lab values normalized to 20°C	Yes, Review Report 2003
Transformation rate	0.011342 Flufenacet→ sink	0.010922 Flufenacet→ FOE-sulfonic acid 0.004951 FOE-sulfonic acid→ sink (Tier1) 0.031942 FOE-sulfonic acid→ sink (Tier2)	0.019744 Flufenacet→ FOE-oxalate 0.105022 FOE-oxalate→ sink (Tier1)	Values re-calculated with the endpoints shown in this table (DT50 16.5d for fft)
K_{foc} (mL/g)	187 (n=5)	9.7 (n=3)	10.6 (n=3)	Geomean is used, according to the EFSA Guidance on DegT50

Compound	Flufenacet	FOE-sulfonic acid (M2)	FOE-oxalate (M1)	Value in accordance with EU endpoint y/n/ Reference*
				(2014)
K_{fom}(mL/g)/	108.46	5.62	6.14	Calculated with the formula Koc = 1.724 * Kom
1/n	0.89 (n=5)	1.04 (n=3)	0.91 (n=3)	Yes, Review Report 2003
Plant uptake factor	0	0	0	Yes, Review Report 2003
Formation fraction	N/A	0.26 Flufenacet →FOE-sulfonic acid 1 FOE-sulfonic acid → sink	0.47 Flufenacet → FOE-oxalate 1 FOE-oxalate → sink	Yes, Review Report 2003

**This DT50 value for FOE-sulfonic acid originates from a study from the notifier in which a kinetic re-evaluation of the data from the field dissipation studies from the DAR of flufenacet is performed (Hammel K, 2008. Kinetic evaluation of the dissipation of flufenacet and its metabolite flufenacet-sulfonic acid in soil based on field studies. Bayer Crop Science, MEF-08/266 ; 2008-08-25). As this report is a non-GLP recalculation of already out of protection data, the study is not subject of data protection and it can be used in this dossier.

FOCUS PEARL Tier 1 PECgw

Table 0-8: PEC_{gw} for Flufenacet, FOE-sulfonic acid and FOE-oxalate on winter cereals (with FOCUS PEARL 4.4.4 Tier 1) uses 1-6 (1.5L/ha GLOB1310aH pre-emergence)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Flufenacet	FOE-sulfonic acid (M2)	FOE-oxalate (M1)
Winter cereals	Châteaudun	0.000000	**6.751429**	0.005610
	Hamburg	0.000000	**6.409191**	0.090299
	Jokioinen	0.000000	**10.666230**	0.064711
	Kremsmünster	0.000000	**3.956569**	0.015183
	Okehampton	0.000000	**3.524682**	**0.100065**
	Piacenza	0.000000	**3.897852**	0.013328
	Porto	0.000000	**3.031534**	0.089267
	Sevilla	0.000000	**3.237583**	0.000000
	Thiva	0.000000	**7.158730**	0.000766

Table 0-9: PEC_{gw} for Flufenacet, FOE-sulfonic acid and FOE-oxalate on winter cereals (with FOCUS PEARL 4.4.4 Tier 1) uses 7-12 (2L/ha GLOB1310aH pre-emergence)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Flufenacet	FOE-sulfonic acid (M2)	FOE-oxalate (M1)
Winter cereals	Châteaudun	0.000000	**8.534706**	**0.128810**
	Hamburg	0.000000	**14.199116**	0.093563
	Jokioinen	0.000000	**5.271180**	0.021653
	Kremsmünster	0.000000	**4.697541**	**0.140168**
	Okehampton	0.000000	**5.185605**	0.018943
	Piacenza	0.000000	**4.041841**	**0.125404**
	Porto	0.000000	**4.307256**	0.000000
	Sevilla	0.000000	**9.534734**	0.001145
	Thiva	0.000000	**8.983889**	0.008146

FOCUS PEARL Tier 2 PECgw

Table 0-10: PEC_{gw} for Flufenacet, FOE-sulfonic acid and FOE-oxalate on winter cereals (with FOCUS PEARL 4.4.4 Tier 2) uses 1-6 (1.5L GLOB1310aH pre-emergence)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Flufenacet	FOE-sulfonic acid (M2)	FOE-oxalate (M1)
Winter cereals	Châteaudun	0.000000	**0.444366**	0.005612
	Hamburg	0.000000	**1.302630**	0.090289
	Jokioinen	0.000000	**2.064451**	0.064708
	Kremsmünster	0.000000	**0.641093**	0.015181
	Okehampton	0.000000	**1.069886**	**0.100059**
	Piacenza	0.000000	**0.383119**	0.013331
	Porto	0.000000	**0.734143**	0.089255
	Sevilla	0.000000	0.021497	0.000000
	Thiva	0.000000	**0.151109**	0.000771

Table 0-11: PEC_{gw} for Flufenacet, FOE-sulfonic acid and FOE-oxalate on winter cereals (with FOCUS PEARL 4.4.4 Tier 2) uses 7-12 (2L/ha GLOB1310aH pre-emergence)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Flufenacet	FOE-sulfonic acid (M2)	FOE-oxalate (M1)
Winter cereals	Châteaudun	0.000000	**0.590258**	0.008147
	Hamburg	0.000000	**1.731376**	**0.128799**
	Jokioinen	0.000000	**2.724940**	0.096559
	Kremsmünster	0.000000	**0.851998**	0.021653
	Okehampton	0.000000	**1.421083**	**0.140159**
	Piacenza	0.000000	**0.510256**	0.018946
	Porto	0.000000	**0.977973**	**0.125384**
	Sevilla	0.000000	0.028515	0.000000
	Thiva	0.000000	**0.201205**	0.001150

Based on Tier 2 FOCUS PEARL:

- PECgw for flufenacet are below 0.1 µg/L in all scenarios
- PECgw for flufenacet sulfonic acid (M2) exceed 0.1 µg/L in all scenarios, except Sevilla, (max. 2.724940 µg/L, for use of 2L GLOB1310aH/ha at pre-emergence in Joikionen scenario)
- PECgw for flufenacet oxalate (M1) exceed 0.1 µg/L in some scenarios (max. 0.140159 µg/L, for use of 2L GLOB1310aH/ha at pre-emergence in Okehampton scenario)

Please refer to section B10 for the assessment of the relevance of flufenacet metabolites.

FOCUS PELMO Tier 1 PECgw

Table 0-12: PEC_{gw} for Flufenacet, FOE-sulfonic acid and FOE-oxalate on winter cereals (with FOCUS PELMO 5.5.3 Tier 1) uses 1-6 (1.5L GLOB1310aH pre-emergence)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Flufenacet	**FOE-sulfonic acid (M2)**	**FOE-oxalate (M1)**
Winter cereals	Châteaudun	0.000	**5.802**	0.000
	Hamburg	0.000	**6.168**	0.000
	Jokioinen	0.000	**7.510**	0.000
	Kremsmünster	0.000	**4.633**	0.000
	Okehampton	0.000	**3.550**	0.000
	Piacenza	0.000	**4.993**	0.000
	Porto	0.000	**2.837**	0.001
	Sevilla	0.000	**2.379**	0.000
	Thiva	0.000	**4.413**	0.000

Table 0-13: PEC_{gw} for Flufenacet, FOE-sulfonic acid and FOE-oxalate on winter cereals (with FOCUS PELMO 5.5.3 Tier 1) uses 7-12 (2L GLOB1310aH pre-emergence)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Flufenacet	**FOE-sulfonic acid (M2)**	**FOE-oxalate (M1)**
Winter cereals	Châteaudun	0.000	**7.708**	0.000
	Hamburg	0.000	**8.210**	0.000
	Jokioinen	0.000	**9.987**	0.000
	Kremsmünster	0.000	**6.154**	0.000
	Okehampton	0.000	**4.725**	0.000
	Piacenza	0.000	**6.635**	0.000
	Porto	0.000	**3.764**	0.000
	Sevilla	0.000	**3.151**	0.000
	Thiva	0.000	**5.863**	0.000

FOCUS PELMO Tier 2 PECgw

Table 0-14: PEC_{gw} for Flufenacet, FOE-sulfonic acid and FOE-oxalate on winter cereals (with FOCUS PELMO 5.5.3 Tier 2) uses 1-6 (1.5L GLOB1310aH pre-emergence)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Flufenacet	FOE-sulfonic acid (M2)	FOE-oxalate (M1)
Winter cereals	Châteaudun	0.000	**0.343**	0.000
	Hamburg	0.000	**1.403**	0.000
	Jokioinen	0.000	**2.026**	0.000
	Kremsmünster	0.000	**0.713**	0.000
	Okehampton	0.000	**1.122**	0.000
	Piacenza	0.000	**0.531**	0.000
	Porto	0.000	**0.994**	0.001
	Sevilla	0.000	**0.156**	0.000
	Thiva	0.000	**0.161**	0.000

Table 0-15: PEC_{gw} for Flufenacet, FOE-sulfonic acid and FOE-oxalate on winter cereals (with FOCUS PELMO 5.5.3 Tier 2) uses 7-12 (2L GLOB1310aH pre-emergence)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Flufenacet	FOE-sulfonic acid (M2)	FOE-oxalate (M1)
Winter cereals	Châteaudun	0.000	**0.454**	0.000
	Hamburg	0.000	**1.864**	0.000
	Jokioinen	0.000	**2.682**	0.000
	Kremsmünster	0.000	**0.944**	0.000
	Okehampton	0.000	**1.491**	0.000
	Piacenza	0.000	**0.704**	0.000
	Porto	0.000	**1.325**	0.000
	Sevilla	0.000	**0.207**	0.000
	Thiva	0.000	**0.214**	0.000

Based on Tier 2 FOCUS PELMO:

- PECgw for flufenacet are below 0.1 µg/L in all scenarios
- PECgw for flufenacet sulfonic acid (M2) exceed 0.1 µg/L in all scenarios (max. 2.682 µg/L, for use of 2L GLOB1310aH/ha at pre-emergence)
- PECgw for flufenacet oxalate (M1) are below 0.1 µg/L in all scenarios

Please refer to section B10 for the assessment of the relevance of flufenacet metabolites.

8.9 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

Evaluation by zRMS	PECsw (KCP 9.2.5)
Inputs for Modelling	For the active substances aclonifen and flufenacet as well as for both metabolites of flufenacet the calculations presented here are accepted. Predicted environmental concentrations in surface water (PEC_{sw}) and sediment (PEC_{sed}) has been calculated for aclonifen and flufenacet and its metabolites after single application of the product GLOB1310aH to winter cereals in two applications rates: 1.5l product/ha and 2.0 product/ha, considering the pathways spray drift, drainage and runoff. The PEC_{SW} and PEC_{sed} were calculated in compliance with relevant FOCUS scenarios in stepwise procedure (Steps 1, 2, 3 and 4). zRMS ~~did not~~ has evaluated the calculations obtained with the VFSMOD model and found them to be correct. However the conclusion on the applicable mitigation measures coming from this modelling is competence of each MS. According to the document prepared after meeting the Southern Member States Steering Committee (SMS SC) titled "Quantitative Mitigation of Surface Runoff Pesticides with Vegetative Filter Strips using VFSMOD" it was indicated that the VFS-MOD is already included in the SWAN-VFSMod package of FOCUSsw. In the meeting on 12 May 2021 agreed that the use of this tool for the calculation of PECsw at SMS level and for the proposal of RMM at zonal level can be used by applicants in their proposal of DRR for the application of authorization of plant protection products. However the use of FOCUS Landscape Guidance is always mandatory, zRMS when in its assessment will propose the risk mitigation measures established by the FOCUS Landscape Guidance and also the risk mitigation measures calculated with the VFS-MOD, the acceptance of the proposed risk mitigation measures for the authorization of the plant protection product is a competence of each MS. The above can also be applied to the central zone. zRMS evaluated also calculations received from the exposure patter analysis model (EPAT) as a refinement for the aclonifen exposure. The presented assumptions and calculations are acceptable. Calculations were carried out for a single application of the product GLOB1310aH to winter cereals, taking into account the application rates according to GAP. **GLOB1310aH** Calculations of PEC_{SW} values for formulation has been provided by Applicant. The calculations are accepted. Presented calculations may be used for risk assessment.
Agreed endpoints	Please refer to Tables 8.9-3 and 8.9-12.
Implication for risk assessment	Please refer to Part B, Section 9 of this dRR.

8.9.1 Justification for new endpoints

Deviations from the EU agreed endpoints are explained in the tables below for Aclonifen and Flufenacet (and its metabolites) and are in agreement with the current FOCUS Guidance.

8.9.2 Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5)

Table 0-1: Input parameters related to application for $PEC_{SW/SED}$ calculations

Plant protection product	GLOB1310aH	GLOB1310aH
Use No.	1	2
Growth stage	BBCH 00-09	BBCH 00-09
Crop	Winter cereals	Winter cereals
Application rate (g as/ha)	810 g Aclonifen/ha 90 g Flufenacet/ha	1080 g Aclonifen/ha 120 g Flufenacet/ha
Number of applications/interval (d)	1/-	1/-
Application window	Autumn: Oct-Feb (relevant for STEP 1 and 2 only)	Autumn: Oct-Feb (relevant for STEP 1 and 2 only)
Application method	Ground spray	Ground spray
CAM (Chemical application method)	1-soil linear	1-soil linear
Soil depth (cm)	4	4
Models used for calculation	FOCUS STEP 1 & 2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXSWA v5.5.3; SWAN 5.00	FOCUS STEP 1 & 2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXSWA v5.5.3; SWAN 5.00

Table 0-2: FOCUS Step 3 Scenario related input parameters for $PEC_{sw/sed}$ calculations for the application of GLOB1310aH

Crop	Scenario	Application window used in modelling, pre - emergence use 1 and 3
Winter Cereals	D1	11 Sep – 11 Oct (254-284)
	D2	11 Oct – 10 Nov (284-314)
	D3	7 Nov – 7 Dec (311-341)
	D4	8 Sep – 8 Oct (251-281)
	D5	27 Oct – 26 Nov (300-330)
	D6	16 Nov – 16 Dec (320-350)
	R1	29 Oct – 28 Nov (303-332)
	R3	17 Nov – 17 Dec (321-351)
	R4	27 Oct – 26 Nov (300-330)

8.9.2.1 Aclonifen and its metabolites

Table 0-3: Input parameters related to active substance Aclonifen for $PEC_{sw/sed}$ calculations STEP 1/2 and 3(/4)

Compound	Aclonifen	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	264.7	Y, EFSA 2008
Saturated vapour pressure (Pa) / Temperature (20°C)	1.6×10^{-5}	Y
Water solubility (mg/L) / Temperature (20°C)	1.4	Y, EFSA 2008
K_{foc} (mL/g)	5318 (worst case for PECsw)* 10612 (worst case for PECsed)*	Y, EFSA 2008
Freundlich Exponent 1/n	0.878 (associated with Kfoc 5318)* 1.003 (associated with Kfoc 10612)*	Y, EFSA 2008
Plant Uptake	0	Y, EFSA 2008
$DT_{50,soil}$ (d)	62.3	During the EU review, the wrong geometric mean of the lab DT_{50} was used. Here the correct geometric mean was used in accordance with EFSA Journal 2014;12(5):3662.
$DT_{50,water}$ (d)**	17.3 d for Step 2 1000 d for Step 3 and 4	Y, EFSA 2008
$DT_{50,sed}$ (d)**	1000 d for Step 2 17.3 d for Step 3 and 4	Y, EFSA 2008
$DT_{50,whole\ system}$ (d)**	17.3	Y, EFSA 2008

*Two sets of simulations are conducted: the 1st one using the lowest value of 5318 mL/g (worst-case for PECsw), associated with 1/n of 0.878 and the 2nd one using the highest value of 10612 mL/g (worst-case for PECsed), associated with 1/n of 1.003.
**The water DT50 value of 4.4 days is a dissipation value and should not be used for modelling. According to FOCUS SW 2015 recommendations, the geomean total system DT50 should be used in Step 2 for both water ad sediment compartments, namely 17.3 days. In Step 3-4, considering that Kfoc of aclonifen is above 2000mL/g, the geomean total system DT50 should be ascribed to the sediment compartment, and a default value of 1000 days should be ascribed to the water compartment. According to EFSA DegT50 guidance document (2014)[5] and to EFSA Scientific Report on Aclonifen (2008), the geomean soil DT50 of 62.3 days (geomean of laboratory DT50 values normalized to 20°C pF2) should be used.

$PEC_{sw/sed}$ Aclonifen

Table 0-4: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for Aclonifen following single application of GLOB1310aH to winter cereals – 1.5L GLOB1310aH/ha (810g Aclonifen/ha, Pre-emergence)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)*
Step 1	---	40.8211	-	30.3703	23.3418	1770
Step 2						

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)*
Northern Europe	Jun-Sep	7.6138	-	6.9287	6.6446	386.1422
	Oct-Feb	17.1896	-	16.0271	15.3905	895.0279
Southern Europe	Jun-Sep	10.5087	-	9.9615	9.5599	555.7708
	Oct-Feb	13.9977	-	12.9943	12.4752	725.3994
Step 3						
D1	ditch	5.1550	Drift	3.7950	2.5980	24.8128
D1	stream	6.0760	Drift	0.7642	0.2576	4.7752
D2	ditch	5.1600	Drift	3.7990	1.4430	19.7135
D2	stream	6.1870	Drift	4.5600	1.6610	23.5368
D3	ditch	5.0820	Drift	0.5824	0.1964	3.2885
D4	pond	0.2625	Drift	0.2350	0.1985	2.1558
D4	stream	5.9370	Drift	0.2433	0.0814	1.5804
D5	pond	0.2625	Drift	0.2361	0.2013	2.1919
D5	stream	6.4060	Drift	0.3476	0.1165	2.0275
D6	ditch	5.1380	Drift	3.4460	1.3570	14.3827
R1	pond	0.2928	Run-off	0.2680	0.2331	3.7947
R1	stream	4.5120	Drift	0.2186	0.0734	9.6527
R3	stream	6.2660	Drift	0.4354	0.2111	302.9224
R4	stream	4.5400	Drift	0.2449	0.0818	6.0021

Table 0-5: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for Aclonifen following single application of GLOB1310aH to winter cereals – 2L GLOB1310aH/ha (1080g Aclonifen/ha, Pre-emergence)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	54.4281	-	40.4938	31.1224	2370
Step 2						
Northern Europe	Jun-Sep	10.1518	-	9.2383	8.8595	514.8563
	Oct-Feb	22.9194	-	21.3695	20.5207	1190
Southern Europe	Jun-Sep	14.4077	-	13.2820	12.7466	741.0277
	Oct-Feb	18.6636	-	17.3258	16.6336	967.1991
Step 3						
D1	ditch	6.8780	Drift	5.0700	3.4860	33.0966
D1	stream	8.1060	Drift	1.0200	0.3439	6.3699
D2	ditch	6.8840	Drift	5.0750	1.9300	26.2887
D2	stream	8.2540	Drift	6.0910	2.2200	31.3906

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
D3	ditch	6.7800	Drift	0.7773	0.2622	4.3859
D4	pond	0.3502	Drift	0.3137	0.2653	2.8756
D4	stream	7.9210	Drift	0.3246	0.1086	2.1072
D5	pond	0.3503	Drift	0.3151	0.2690	2.9244
D5	stream	8.5460	Drift	0.4638	0.1554	2.7033
D6	ditch	6.8540	Drift	4.6030	1.8150	19.1907
R1	pond	~~0.4002~~ 0.3583	Run-off	~~0.3663~~ 0.3260	~~0.3188~~ 0.2814	~~5.0620~~ 4.6760
R1	stream	~~6.0200~~ 4.4650	Drift	0.3008	0.1010	~~12.8703~~ 9.9010
R3	stream	~~8.3590~~ 6.2000	Drift	0.6023	~~0.2890~~ 0.2696	~~403.8253~~ 358.6000
R4	stream	~~6.0570~~ 4.4920	Drift	0.3381	0.1130	~~8.0021~~ 6.1200

FOCUS Step 4 (according to Landscape and Mitigation Report)– Aclonifen

The FOCUS guidance on surface water 1.4 mentions that when calculating Step 4 PECsw where spray drift is mitigated, the re-deposition of volatilised substance to surface water should be accounted for. The vapour pressure at 20 °C of the active substance aclonifen is between 10^{-5} and 10^{-4} Pa. Hence, aclonifen is regarded as semivolatile (volatilisation only from plant surfaces). Therefore exposure of adjacent surface waters and terrestrial ecosystems by the compound due to volatilization with subsequent deposition should be considered. However as aclonifen formulated in GLOB1310aH is intended only for use as a pre-emergence herbicide (BBCH 00-09), corresponding to a crop interception of 0%, an assessment of volatilization with subsequent deposition from plant surfaces is therefore not relevant for Step 4 PECsw calculations.

For vegetated filter strip (VFS), Table 7 of Volume 1 of the FOCUS Landscape and Mitigation Report (LMR) gives 90th percentile reductions in volume of run-off /eroded mass, to be entered as a fraction. (e.g. for 10 m buffer = 60% (run-off), 85% (eroded mass), entry being 0.6 and 0.85; and for 20 m buffer = 80% (run-off), 95% (eroded mass), entry being 0.8 and 0.95 and for 15m stripes= 70% (run-off), 90% (eroded mass). This approach is commonly accepted all over EU.

Table 0-6: Global maximum PEC_{sw} values for aclonifen, following single application of GLOB1310aH to winter cereals according to the ~~Southern~~ Central EU zone GAP according to surface water Step 4 – 1.5L GLOB1310aH/ha (810g Aclonifen/ha) at pre-emergence

PEC_{sw} (µg/L)	Scenario	STEP 4 Aclonifen								
Nozzle reduction	Vegetative strip (m)	None	None	None	None	None	10	10	10	20
	No spray buffer (m)	1/3	5	10	15	20	10	50	100	20
None	D1 ditch	5.1550	1.3960	0.7395	0.5050	0.3839	-	-	-	-

PECsw (µg/L)	**Scenario**	**STEP 4 Aclonifen**								
Nozzle reduction	Vegetative strip (m)	None	None	None	None	None	10	10	10	20
	No spray buffer (m)	1/3	5	10	15	20	10	50	100	20
50 %		2.5760	0.6973	0.3694	0.2522	0.1918	-	-	-	-
75 %		1.2870	0.3483	0.1846	0.1260	0.0958	-	-	-	-
90 %		0.5142	0.1392	0.0737	0.0503	0.0383	-	-	-	-
None	D1 stream	6.0760	1.6450	0.8718	0.5954	0.4525	-	-	-	-
50 %		3.0370	0.8219	0.4357	0.2974	0.2261	-	-	-	-
75 %		1.5170	0.4108	0.2176	0.1485	0.1129	-	-	-	-
90 %		0.6061	0.1640	0.0869	0.0593	0.0451	-	-	-	-
None	D2 ditch	5.1600	1.3970	0.7403	0.5055	0.3843	-	-	-	-
50 %		2.5790	0.6980	0.3698	0.2525	0.1920	-	-	-	-
75 %		1.2880	0.3487	0.1848	0.1261	0.0959	-	-	-	-
90 %		0.5147	0.1393	0.0738	0.0504	0.0383	-	-	-	-
None	D2 stream	6.1870	1.6750	0.8877	0.6063	0.4608	-	-	-	-
50 %		3.0920	0.8369	0.4437	0.3028	0.2303	-	-	-	-
75 %		1.5450	0.4183	0.2216	0.1513	0.1150	-	-	-	-
90 %		0.6172	0.1670	0.0885	0.0604	0.0459	-	-	-	-
None	D3 ditch	5.0820	1.3760	0.7290	0.4978	0.3785	-	-	-	-
50 %		2.5400	0.6874	0.3642	0.2487	0.1891	-	-	-	-
75 %		1.2690	0.3434	0.1820	0.1242	0.0944	-	-	-	-
90 %		0.5069	0.1372	0.0727	0.0496	0.0377	-	-	-	-
None	D4 pond	0.2625	0.1515	0.1089	0.0868	0.0727	-	-	-	-
50 %		0.1311	0.0757	0.0544	0.0433	0.0363	-	-	-	-
75 %		0.0655	0.0378	0.0272	0.0216	0.0181	-	-	-	-
90 %		0.0262	0.0151	0.0108	0.0094	0.0092	-	-	-	-
None	D4 stream	5.9370	1.6080	0.8519	0.5818	0.4422	-	-	-	-
50 %		2.9670	0.8032	0.4258	0.2906	0.2210	-	-	-	-
75 %		1.4830	0.4014	0.2126	0.1451	0.1104	-	-	-	-
90 %		0.5923	0.1603	0.0849	0.0699	0.0699	-	-	-	-
None	D5 pond	0.2625	0.1515	0.1089	0.0868	0.0727	-	-	-	-
50 %		0.1311	0.0757	0.0544	0.0433	0.0363	-	-	-	-
75 %		0.0655	0.0378	0.0272	0.0217	0.0181	-	-	-	-
90 %		0.0262	0.0151	0.0109	0.0086	0.0072	-	-	-	-
None	D5 stream	6.4060	1.7350	0.9192	0.6278	0.4771	-	-	-	-
50 %		3.2020	0.8666	0.4594	0.3135	0.2384	-	-	-	-
75 %		1.6000	0.4331	0.2294	0.1566	0.1191	-	-	-	-
90 %		0.6390	0.1729	0.0916	0.0626	0.0476	-	-	-	-
None	D6 ditch	5.1380	1.3910	0.7370	0.5033	0.3826	-	-	-	-
50 %		2.5670	0.6949	0.3682	0.2514	0.1963	-	-	-	-
75 %		1.2830	0.3472	0.1963	0.1963	0.1963	-	-	-	-
90 %		0.5125	0.1963	0.1963	0.1963	0.1963	-	-	-	-

PECsw (µg/L)	Scenario	STEP 4 Aclonifen								
Nozzle reduction	Vegetative strip (m)	None	None	None	None	None	10	10	10	20
	No spray buffer (m)	1/3	5	10	15	20	10	50	100	20
None	R1 pond	0.2928	0.2534	0.2384	0.2307	0.2258	0.1203	0.0941	0.0884	0.0730
50 %		0.2462	0.2269	0.2195	0.2158	0.2134	0.09981	0.0876	0.0848	0.0530
75 %		0.2234	0.2139	0.2103	0.2084	0.2072	0.09041	0.0844	0.0830	0.0468
90 %		0.2099	0.2062	0.2048	0.2040	0.2036	0.08488	0.0825	0.0820	0.0431
None	R1 stream	4.5120	1.2340	1.2340	1.2340	1.2340	0.6474	0.5520	0.5520	0.3361
50 %		2.2550	1.2340	1.2340	1.2340	1.2340	0.552	0.5520	0.5520	0.2873
75 %		1.2340	1.2340	1.2340	1.2340	1.2340	0.552	0.5520	0.5520	0.2873
90 %		1.2340	1.2340	1.2340	1.2340	1.2340	0.552	0.5520	0.5520	0.2873
None	R3 stream	6.2660	1.6970	1.4080	1.4080	1.4080	0.9086	0.6420	0.6420	0.4667
50 %		3.1320	1.4080	1.4080	1.4080	1.4080	0.642	0.6420	0.6420	0.3364
75 %		1.5650	1.4080	1.4080	1.4080	1.4080	0.642	0.6420	0.6420	0.3364
90 %		1.4080	1.4080	1.4080	1.4080	1.4080	0.642	0.6420	0.6420	0.3364
None	R4 stream	4.5400	1.8270	1.8270	1.8270	1.8270	0.9524	0.8238	0.8238	0.4299
50 %		2.2690	1.8270	1.8270	1.8270	1.8270	0.8238	0.8238	0.8238	0.4299
75 %		1.8270	1.8270	1.8270	1.8270	1.8270	0.8238	0.8238	0.8238	0.4299
90 %		1.8270	1.8270	1.8270	1.8270	1.8270	0.8238	0.8238	0.8238	0.4299

Table 0-7: Global maximum PECsw values for aclonifen, following single application of GLOB1310aH to winter cereals according to the ~~Southern~~ Central EU zone GAP according to surface water Step 4 – 2L GLOB1310aH/ha (1080g Aclonifen/ha) at pre-emergence

PECsw (µg/L)	Scenario	STEP 4 Aclonifen										
Nozzle reduction	Vegetative strip (m)	None	None	None	None	None	None	10	10	10	20	20
	No spray buffer (m)	1/3	5	10	15	20	50	10	50	100	20	50
None	D1 ditch	6.8780	1.8610	0.9864	0.6735	0.5122	0.2118	-	-	-	-	-
50 %		3.4360	0.9299	0.4928	0.3365	0.2558	-	-	-	-	-	-
75 %		1.7170	0.4647	0.2462	0.1681	0.1278	-	-	-	-	-	-
90 %		0.6861	0.1856	0.0983	0.0671	0.0511	-	-	-	-	-	-
None	D1 stream	8.1060	2.1940	1.1630	0.7940	0.6038	0.2497	-	-	-	-	-
50 %		4.0500	1.0960	0.5808	0.3965	0.3016	-	-	-	-	-	-
75 %		2.0240	0.5478	0.2902	0.1981	0.1506	-	-	-	-	-	-
90 %		0.8086	0.2188	0.1159	0.0792	0.0602	-	-	-	-	-	-
None	D2 ditch	6.8840	1.8630	0.9874	0.6743	0.5128	0.2121	-	-	-	-	-

PECsw (µg/L)	**Scenario**	**STEP 4 Aclonifen**										
Nozzle reduction	Vegetative strip (m)	None	None	None	None	None	None	10	10	10	20	20
	No spray buffer (m)	1/3	5	10	15	20	50	10	50	100	20	50
50 %		3.4400	0.9309	0.4933	0.3369	0.2562	-	-	-	-	-	-
75 %		1.7180	0.4653	0.2465	0.1683	0.1280	-	-	-	-	-	-
90 %		0.6868	0.1859	0.0985	0.0673	0.0512	-	-	-	-	-	-
None	D2 stream	8.2540	2.2340	1.1840	0.8085	0.6149	0.2543	-	-	-	-	-
50 %		4.1240	1.1160	0.5914	0.4038	0.3071	-	-	-	-	-	-
75 %		2.0610	0.5578	0.2955	0.2018	0.1534	-	-	-	-	-	-
90 %		0.8234	0.2228	0.1181	0.0806	0.0613	-	-	-	-	-	-
None	D3 ditch	6.7800	1.8350	0.9724	0.6640	0.5050	0.2088	-	-	-	-	-
50 %		3.3880	0.9167	0.4858	0.3317	0.2522	-	-	-	-	-	-
75 %		1.6920	0.4581	0.2427	0.1657	0.1260	-	-	-	-	-	-
90 %		0.6763	0.1830	0.0969	0.0662	0.0503	-	-	-	-	-	-
None	D4 pond	0.3502	0.2021	0.1452	0.1157	0.0969	0.0504	-	-	-	-	-
50 %		0.1749	0.1010	0.0725	0.0578	0.0484	-	-	-	-	-	-
75 %		0.0874	0.0504	0.0362	0.0289	0.0242	-	-	-	-	-	-
90 %		0.0349	0.0201	0.0145	0.0137	0.0133	-	-	-	-	-	-
None	D4 stream	7.9210	2.1440	1.1360	0.7759	0.5900	0.2440	-	-	-	-	-
50 %		3.9580	1.0710	0.5676	0.3875	0.2947	-	-	-	-	-	-
75 %		1.9770	0.5353	0.2836	0.1936	0.1472	-	-	-	-	-	-
90 %		0.7902	0.2138	0.1133	0.1009	0.1009	-	-	-	-	-	-
None	D5 pond	0.3503	0.2021	0.1453	0.1157	0.0969	0.0504	-	-	-	-	-
50 %		0.1749	0.1010	0.0726	0.0578	0.0484	-	-	-	-	-	-
75 %		0.0874	0.0504	0.0362	0.0289	0.0242	-	-	-	-	-	-
90 %		0.0349	0.0201	0.0145	0.0115	0.0097	-	-	-	-	-	-
None	D5 stream	8.5460	2.3140	1.2260	0.8372	0.6366	0.2633	-	-	-	-	-
50 %		4.2700	1.1560	0.6124	0.4181	0.3180	-	-	-	-	-	-
75 %		2.1340	0.5775	0.3060	0.2089	0.1588	-	-	-	-	-	-
90 %		0.8526	0.2307	0.1222	0.0835	0.0635	-	-	-	-	-	-
None	D6 ditch	6.8540	1.8550	0.9830	0.6712	0.5105	0.2992	-	-	-	-	-
50 %		3.4250	0.9268	0.4911	0.3353	0.2992	-	-	-	-	-	-
75 %		1.7110	0.4632	0.2992	0.2992	0.2992	-	-	-	-	-	-
90 %		0.6837	0.2992	0.2992	0.2992	0.2992	-	-	-	-	-	-
None	R1 pond	0.4002	0.3471	0.3270	0.3166	0.3100	0.2939	0.1626	0.1290	0.1214	0.0974	0.0733
50 %		0.3374	0.3114	0.3015	0.2964	0.2932	-	0.1368	0.1203	0.1166	0.0726	0.0645
75 %		0.3067	0.2939	0.2890	0.2865	0.2849	-	0.1241	0.1160	0.1142	0.0642	0.0602

PECsw (µg/L)	**Scenario**	**STEP 4 Aclonifen**										
Nozzle reduction	Vegetative strip (m)	None	None	None	None	None	None	10	10	10	20	20
	No spray buffer (m)	1/3	5	10	15	20	50	10	50	100	20	50
90 %		0.2886	0.2835	0.2816	0.2806	0.2800	-	0.1167	0.1135	0.1128	0.0593	0.0577
None	R1 stream	6.0200	1.7050	1.7050	1.7050	1.7050	1.7050	0.8636	0.7625	0.7625	0.4484	0.3968
50 %		3.0080	1.7050	1.7050	1.7050	1.7050	-	0.7625	0.7625	0.7625	0.3968	0.3968
75 %		1.7050	1.7050	1.7050	1.7050	1.7050	-	0.7625	0.7625	0.7625	0.3968	0.3968
90 %		1.7050	1.7050	1.7050	1.7050	1.7050	-	0.7625	0.7625	0.7625	0.3968	0.3968
None	R3 stream	8.3590	2.2630	1.9510	1.9510	1.9510	1.9510	1.199	0.8895	0.8895	0.6227	0.4663
50 %		4.1770	1.9510	1.9510	1.9510	1.9510	-	0.8895	0.8895	0.8895	0.4663	0.4663
75 %		2.0870	1.9510	1.9510	1.9510	1.9510	-	0.8895	0.8895	0.8895	0.4663	0.4663
90 %		1.9510	1.9510	1.9510	1.9510	1.9510	-	0.8895	0.8895	0.8895	0.4663	0.4663
None	R4 stream	6.0570	2.5230	2.5230	2.5230	2.5230	2.5230	1.138	1.1380	1.1380	0.5939	0.5939
50 %		3.0260	2.5230	2.5230	2.5230	2.5230	-	1.138	1.1380	1.1380	0.5939	0.5939
75 %		2.5230	2.5230	2.5230	2.5230	2.5230	-	1.138	1.1380	1.1380	0.5939	0.5939
90 %		2.5230	2.5230	2.5230	2.5230	2.5230	-	1.138	1.1380	1.1380	0.5939	0.5939

Step 4 VFSMOD calculations

In addition to the calculations presented above (according to the standard FOCUS Landscape and Mitigation Report), the applicant also used VFSMod calculations to reduce run-off as this tool is now accepted in some Member States. VFSMod is presented as a Tier 2 refinement.

Table 0-8: Global maximum PEC_{sw} values for aclonifen, following single application of GLOB1310aH to winter cereals according to the ~~Southern~~ Central EU zone GAP according to surface water Step 4 VFSMOD– 1.5L GLOB1310aH/ha (810g Aclonifen/ha) at pre-emergence

PECsw (µg/L)	**Scenario**	**STEP 4 Aclonifen**	
Nozzle reduction	Vegetative strip (m)	10	20
	No spray buffer (m)	10	20
None	R1 pond	0.1088	0.0726
50 %		0.0543	0.0363
75 %		0.0271	0.0181
90 %		0.0108	0.0072
None	R1 stream	0.6474	0.3360
50 %		0.3235	0.1679
75 %		0.1616	0.0839

PECsw (µg/L)	Scenario	STEP 4 Aclonifen	
Nozzle reduction	Vegetative strip (m)	10	20
	No spray buffer (m)	10	20
90 %		0.0645	0.0335
None	R3 stream	0.8991	0.4667
50 %		0.5188	0.3364
75 %		0.5188	0.3364
90 %		0.5188	0.3364
None	R4 stream	0.6514	0.3381
50 %		0.3255	0.1689
75 %		0.1626	0.0844
90 %		0.0649	0.0337

Table 0-9: **Global maximum PEC_{sw} values for aclonifen, following single application of GLOB1310aH to winter cereals according to the ~~Southern~~ Central EU zone GAP according to surface water Step 4 VFSMOD– 2.0L GLOB1310aH/ha (1080g Aclonifen/ha) at pre-emergence**

PECsw (µg/L)	Scenario	STEP 4 Aclonifen	
Nozzle reduction	Vegetative strip (m)	10	20
	No spray buffer (m)	10	20
None	R1 pond	0.1451	0.0968
50 %		0.0725	0.0484
75 %		0.0362	0.0242
90 %		0.0147	0.0096
None	R1 stream	0.8636	0.4484
50 %		0.4313	0.2240
75 %		0.2155	0.1119
90 %		0.0861	0.0447
None	R3 stream	1.1990	0.6227
50 %		0.7184	0.4659
75 %		0.7184	0.4659
90 %		0.7184	0.4659
None	R4 stream	0.8689	0.4511
50 %		0.4340	0.2253
75 %		0.2168	0.1125
90 %		0.0866	0.0450

Exposure pattern analysis (EPAT)

The exposure patter analysis (EPAT) is presented here as a refinement for the aclonifen exposure to the most sensitive aquatic species, namely fish, with a NOEC NOEC of 5 µg/L is based on growth (Please refer to Part B9 Section 9.5 for more details).

The pattern analysis are done taking into account the PECsw Step 4 obtained with the regular landscape mitigation measures (thus the results from the VFSMod were not analysed with EPAT).

For the use 1 (1.5L GLOB1310aH/ha, equivalent to 810g Aclonifen/ha + 90 g Flufenacet/ha at pre-emergence), the PECsw in all scenarios is below the lowest RAC of aclonifen, namely 0.5 µg a.s./ha, when 20m vegetated buffer strip that is also a 20m no spray buffer. When a 10m vegetated buffer strip that is also a 10m no spray buffer in combination with at least 50% drift reduction technology, the PECsw is below the RAC in all scenarios, except R1 Stream, R3 stream, and R4 Stream. Similarly, when a 10m vegetated buffer strip in combination with a 50m no spray buffer, the PECsw is below the RAC in all scenarios, except R1 Stream, R3 stream, and R4 Stream. Thus, the EPAT analysis was done for these 3 scenarios (R1 stream, R3 stream, R4 stream) to show that the exposure to fish to aclonifen is acceptable.

Table 8.9-10: Event summary for Step 4 scenarios R1 stream, R3 stream and R4 stream for use 1 of GLOB1310aH(Aclonifen, 810 g/ha at pre-emergence).

Mitigation measured applied.	Scenario	Number of events	Vent number	Max. conc. (µg L-1)	Duration of event (d)	Interval between events (d)	Total duration of events (d)
10m vbs 10m nsb 50%drt	R1 Stream	2	1	0.5520	0.292	-	0.885
			2	0.5201	0.583	35.667	
	R3 Stream	6	1	0.642	0.458	-	2.167
			2	0.6147	0.875	0.542	
			3	0.5275	0.125	0.166	
			4	0.5875	0.333	0.834	
			5	0.5185	0.334	16.708	
			6	0.5002	0.042	9.666	
	R4 Stream	3	1	0.8238	0.541	-	1.583
			2	0.765	0.417	0.5	
			3	0.5432	0.625	87.542	
10m vbs 50m nsb	R1 Stream	2	1	0.5520	0.292	-	0.885
			2	0.5201	0.583	35.667	
	R3 Stream	6	1	0.642	0.458	-	2.167
			2	0.6147	0.875	0.542	
			3	0.5275	0.125	0.166	
			4	0.5875	0.333	0.834	
			5	0.5185	0.334	16.708	
			6	0.5002	0.042	9.666	
	R4 Stream	3	1	0.8238	0.541	-	1.583
			2	0.765	0.417	0.5	
			3	0.5432	0.625	87.542	

Vbs: vegetated buffer strip; nsb: no spray buffer; drt: drift reduction technology

For the use 2 (2.0L GLOB1310aH/ha, equivalent to 1080g Aclonifen/ha + 120 g Flufenacet/ha at pre-emergence), when a 10m vegetated buffer strip that is also a 10m no spray buffer in combination with at least 75% drift reduction technology is applied the PECsw in all scenarios (except R1 stream, R3 stream, R4 stream) is below the lowest RAC of aclonifen, namely 0.5 µg a.s./ha. When a 20m vegetated buffer strip that is also a 20m no spray buffer in combination with at least 50% drift reduction technology, the PECsw is below the RAC in all scenarios, except R4 Stream. When a 20m vegetated buffer strip in combination with a 50m no spray buffer is respected, the PECsw is below the RAC in all scenarios, except R4

Stream Thus, the EPAT analysis was done for these two mitigation measures.

Table 8.9-11: Event summary for Step 4 scenarios R1 stream, R3 stream and R4 stream for use 2 of GLOB1310aH (Aclonifen, 1080 g/ha at pre-emergence).

Mitigation measured applied.	Scenario	Number of events	Vent number	Max. conc. (µg L-1)	Duration of event (d)	Interval between events (d)	Total duration of events (d)
10m vbs 10m nsb 75%drt	R1 Stream	6	1	0.7625	0.375	-	2.168
			2	0.6136	0.334	33.625	
			3	0.6185	0.334	0.666	
			4	0.7151	0.625	0.625	
			5	0.6796	0.291	32.375	
			6	0.5126	0.209	7.75	
	R3 Stream	6	1	0.8895	0.458	-	2.834
			2	0.851	0.916	0.542	
			3	0.7302	0.209	0.125	
			4	0.8132	0.333	0.75	
			5	0.7162	0.459	16.708	
			6	0.6902	0.459	9.541	
	R4 Stream	6	1	1.138	0.541	-	3.292
			2	1.055	0.417	0.5	
			3	0.7451	0.708	87.542	
			4	0.5469	0.292	2.375	
			5	0.6041	1	23.625	
			6	0.532	0.334	0.041	
20m vbs 20m nsb 50%drt	R4 Stream	2	1	0.5939	0.417	-	0.751
			2	0.549	0.334	0.583	
20m vbs 50m nsb	R4 stream	2	1	0.5939	0.417	-	0.751
			2	0.549	0.334	0.583	

Vbs: vegetated buffer strip; nsb: no spray buffer; drt: drift reduction technology

Metabolites of Aclonifen

Not relevant as Aclonifen does not have relevant water metabolites.

8.9.2.2 Flufenacet and its metabolites

Table 0-12: Input parameters related to active substance Flufenacet and its metabolites for $PEC_{sw/sed}$ calculations

Compound	Flufenacet	FOE-sulfonic acid (M2)	FOE-oxalate (M1)	Thiadone (M9)	Methylsulfide (M5)	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	363.3	275	225.2	170	241	Y/LoEP flufenacet
Saturated vapour pressure (Pa) (at 20°C)	9×10^{-5}	9×10^{-5}	9×10^{-5}	9×10^{-5}	-	Y/LoEP flufenacet

Compound	Flufenacet	FOE-sulfonic acid (M2)	FOE-oxalate (M1)	Thiadone (M9)	Methylsulfide (M5)	Value in accordance to EU endpoint y/n/ Reference
Water solubility (mg/L) 20°C	56	1000	1000	1000	1000 (conservative default value)	Y/LoEP flufenacet
K_{foc} (mL/g)	187 (n=5)	9.7 (n=3)	10.6 (n=3)	0 (conservative default value)	0 (conservative default value)	Geomean is used, according to the EFSA Guidance on DegT50 (2014)
K_{fom} (mL/g)	108.46 (n=5)	5.62 (n=3)	6.148 (n=3)	0 (conservative default value)	0 (conservative default value)	Calculated from Koc = 1.724 * Kom
Freundlich Exponent 1/n	0.89 (mean n=5)	-	-	-	-	Y/LoEP flufenacet
Plant Uptake	0	0	0	0	0	Y/LoEP flufenacet
$DT_{50,soil}$ (d)	16.5	140	6.6	1000	1000	Y/LoEP flufenacet
$DT_{50,water}$ (d)	44.7	1000	1000	1000	1000	Y/LoEP flufenacet
$DT_{50,sed}$ (d)	1000	1000	1000	1000	1000	Y/LoEP flufenacet
$DT_{50,whole\ system}$ (d)	44.7	1000	1000	1000	1000	Y/LoEP flufenacet
Maximum occurrence observed (% molar basis with respect to the parent)	-	3.2% water/sediment	5.4% water/sediment	82%	11.4% in water/sediment	Y/LoEP flufenacet
Max ocurrence in soil	-	26.3%	15.6%	3.9%	0.01% (conservative value)	Y/LoEP flufenacet

According to EFSA Guidance on DegT50 (2014), geometric mean Kfoc values instead of arithmetic mean/median should be used in PEC calculations for the active substances and their metabolites. The following geomean Kfoc values should be used: flufenacet: 187 mL/g ; FOE sulfonic acid: 9.7 mL/g ; FOE oxalate: 10.6 mL/g. No Koc value is available for thiadone and methylsulfide, therefore, a default value of 0 mL/g should be used for both.

$PEC_{sw/sed}$ Flufenacet

Table 0-13: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for Flufenacet following single application of GLOB1310aH to winter cereals – 1.5L GLOB1310aH/ha (90g Flufenacet/ha, Pre-emergence)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)*
Step 1	---	24.8405	-	23.3951	21.0644	44.9039
Step 2						

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)*
Northern Europe	Jun-Sep	4.7308	-	4.4787	4.1107	8.7598
	Oct-Feb	10.8204	-	10.2928	9.4494	20.1394
Southern Europe	Jun-Sep	6.7607	-	6.4167	5.8902	12.5530
	Oct-Feb	8.7905	-	8.3548	7.6698	16.3462
Step 3						
D1	ditch	2.863	Drainage	2.679	2.258	7.141
D1	stream	1.786	Drainage	3.323	2.513	6.49
D2	ditch	6.086	Drainage	1.886	1.457	3.94
D2	stream	3.921	Drift	0.06739	0.02254	0.1681
D3	ditch	0.5689	Drainage	0.2729	0.2619	0.8637
D4	pond	0.2755	Drift	0.2658	0.1775	0.3866
D4	stream	0.4932	Drainage	0.472	0.4429	1.414
D5	pond	0.4799	Drainage	0.3438	0.1832	0.4662
D5	stream	0.6344	Drainage	1.256	0.6493	1.998
D6	ditch	2.504	Run-off	0.03864	0.03514	0.1495
R1	pond	0.04094	Run-off	0.1399	0.04978	0.5195
R1	stream	2.289	Run-off	0.5829	0.2086	3.279
R3	stream	3.051	Run-off	0.08709	0.02905	0.2284
R4	stream	0.8265	Drainage	2.679	2.258	7.141

Table 0-14: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for Flufenacet following single application of GLOB1310aH to winter cereals – 2.0L GLOB1310aH/ha (120g Flufenacet/ha, Pre-emergence)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)*
Step 1	---	33.1207	-	31.1935	28.0859	59.8719
Step 2						
Northern Europe	Jun-Sep	6.3078	-	5.8716	5.4809	11.6797
	Oct-Feb	14.4272	-	13.7238	12.5992	26.8525
Southern Europe	Jun-Sep	9.0143	-	8.5557	7.8537	16.7373
	Oct-Feb	11.7207	-	11.1397	10.2264	21.7949
Step 3						
D1	ditch	3.928	Drainage	3.749	3.102	9.421
D1	stream	2.446	Drainage	2.342	1.967	5.392
D2	ditch	8.474	Drainage	4.612	3.48	8.67
D2	stream	5.449	Drainage	2.619	1.983	5.231

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)*
D3	ditch	0.7586	Drift	0.08987	0.03006	0.2213
D4	pond	0.3683	Drainage	0.365	0.3504	1.136
D4	stream	0.6576	Drift	0.361	0.2361	0.5058
D5	pond	0.6399	Drainage	0.6293	0.5906	1.873
D5	stream	0.8515	Drainage	0.458	0.2464	0.6163
D6	ditch	3.309	Drainage	1.707	0.9058	2.696
R1	pond	0.05526	Run-off	0.05218	0.04746	0.1941
R1	stream	3.113	Run-off	0.1903	0.06762	0.6985
R3	stream	4.155	Run-off	0.7859	0.2805	4.243
R4	stream	1.088	Run-off	0.114	0.03802	0.2979

FOCUS Step 4 – Flufenacet

The FOCUS guidance on surface water 1.4 mentions that when calculating Step 4 PECsw where spray drift is mitigated, the re-deposition of volatilised substance to surface water should be accounted for. The vapour pressure at 20 °C of the active substance flufenacet is between 10^{-5} and 10^{-4} Pa. Hence the active substance flufenacet is regarded as semivolatile (volatilisation only from plant surfaces). Therefore exposure of adjacent surface waters and terrestrial ecosystems by the compound due to volatilization with subsequent deposition should be considered. However as flufenacet formulated in GLOB1310aH is intended only for use as a pre-emergence herbicide (BBCH 00-09), corresponding to a crop interception of 0%, an assessment of volatilization with subsequent deposition from plant surfaces is therefore not relevant for Step 4 PECsw calculations of flufenacet.

As seen in the tables above presenting the PECsw values of flufenacet at Step3, the main route of entrance for most of the scenarios is Drainage. Currently there are no mitigation measures applicable at Step 4 that can reduce the entry of active ingredients in surface water via drainage. Nevertheless, Stap 4 calculations were performed for flufenacet taking into account the mitigation measures that are applicable for aclonifen (in which the risk to aquatic organisms was acceptable). The results are summarized in the tables below.

Table 0-15: Global maximum PEC_{sw} values for flufenacet, following single application of GLOB1310aH to winter cereals according to the ~~Southern~~ Central EU zone GAP according to surface water Step 4 – 1.5L GLOB1310aH/ha (90g Flufenacet/ha) at pre-emergence

PEC_{sw} (µg/L)	Scenario			STEP 4 Flufenacet						
Nozzle	Vegetative strip (m)	None	None	None	None	None	10	10	20	20
reduction	No spray buffer (m)	1/mrt	5	10	15	20	10	50	20	50
None	D1 ditch	-	2.863	2.863	-	-	2.863	2.863	2.863	2.863
50%		2.863	2.863	-	-	-	2.863	-	2.863	-
75%		2.863	2.863	-	-	-	2.863	-	2.863	-
90%		2.863	2.863	-	-	-	2.863	-	2.863	-

None	D1 stream	-	1.786	1.786	-	-	1.786	1.786	1.786	1.786
50%		1.786	1.786	-	-	-	1.786	-	1.786	-
75%		1.786	1.786	-	-	-	1.786	-	1.786	-
90%		1.786	1.786	-	-	-	1.786	-	1.786	-
None	D2 ditch	-	6.086	6.086	-	-	6.086	6.086	6.086	6.086
50%		6.086	6.086	-	-	-	6.086	-	6.086	-
75%		6.086	6.086	-	-	-	6.086	-	6.086	-
90%		6.086	6.086	-	-	-	6.086	-	6.086	-
None	D2 stream	-	3.921	3.921	-	-	3.921	3.921	3.921	3.921
50%		3.921	3.921	-	-	-	3.921	-	3.921	-
75%		3.921	3.921	-	-	-	3.921	-	3.921	-
90%		3.921	3.921	-	-	-	3.921	-	3.921	-
None	D3 ditch	-	0.1542	0.08181	-	-	0.08181	0.0176	0.04251	0.0176
50%		0.3461	0.07712	-	-	-	0.0409	-	0.02125	-
75%		0.1731	0.03854	-	-	-	0.02045	-	0.01062	-
90%		0.06924	0.01542	-	-	-	0.00818	-	0.00425	-
None	D4 pond	-	0.2749	0.2737	-	-	0.2737	0.2717	0.2727	0.2717
50%		0.2746	0.2728	-	-	-	0.2722	-	0.2717	-
75%		0.2726	0.2717	-	-	-	0.2714	-	0.2712	-
90%		0.2715	0.2711	-	-	-	0.271	-	0.2709	-
None	D4 stream	-	0.3269	0.3269	-	-	0.3269	0.3269	0.3269	0.3269
50%		0.4043	0.3269	-	-	-	0.3269	-	0.3269	-
75%		0.3269	0.3269	-	-	-	0.3269	-	0.3269	-
90%		0.3269	0.3269	-	-	-	0.3269	-	0.3269	-
None	D5 pond	-	0.4792	0.478	-	-	0.478	0.4759	0.4769	0.4759
50%		0.4789	0.477	-	-	-	0.4764	-	0.4759	-
75%		0.4769	0.4759	-	-	-	0.4756	-	0.4753	-
90%		0.4756	0.4753	-	-	-	0.4751	-	0.475	-
None	D5 stream	-	0.6344	0.6344	-	-	0.6344	0.6344	0.6344	0.6344
50%		0.6344	0.6344	-	-	-	0.6344	-	0.6344	-
75%		0.6344	0.6344	-	-	-	0.6344	-	0.6344	-
90%		0.6344	0.6344	-	-	-	0.6344	-	0.6344	-
None	D6 ditch	-	2.504	2.504	-	-	2.504	2.504	2.504	2.504
50%		2.504	2.504	-	-	-	2.504	-	2.504	-
75%		2.504	2.504	-	-	-	2.504	-	2.504	-
90%		2.504	2.504	-	-	-	2.504	-	2.504	-
None	R1 pond	-	0.03872	0.03474	-	-	0.02001	0.01336	0.0117	0.008443
50%		0.03778	0.03164	-	-	-	0.01491	-	0.008301	-
75%		0.03119	0.02932	-	-	-	0.0126	-	0.00607	-
90%		0.02878	0.02803	-	-	-	0.01165	-	0.00595	-
None	R1 stream	-	-	-	-	-	1.026	1.026	0.5342	0.5342
50%		-	-	-	-	-	1.026	-	0.5342	-
75%		-	-	-	-	-	1.026	-	0.5342	-

90%		-	-	-	-	-	1.026	-	0.5342	-
None	R3 stream	-	-	-	-	-	1.392	0.7303	0.7303	0.7303
50%		-	-	-	-	-	0.7303	-	0.7303	-
75%		-	-	-	-	-	0.7303	-	0.7303	-
90%		-	-	-	-	-	0.7303	-	0.7303	-
None	R4 stream	-	-	-	-	-	0.3731	0.1949	0.1949	0.1949
50%		-	-	-	-	-	0.1949	-	0.1949	-
75%		-	-	-	-	-	0.1949	-	0.1949	-
90%		-	-	-	-	-	0.1949	-	0.1949	-

Table 0-16: Global maximum PEC_{sw} values for flufenacet, following single application of GLOB1310aH to winter cereals according to the ~~Southern~~ Central EU zone GAP according to surface water Step 4 – 2.0L GLOB1310aH/ha (120g Flufenacet/ha) at pre-emergence

PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Flufenacet**						
Nozzle	Vegetative strip (m)	None	None	None	10	10	20	20
reduction	No spray buffer (m)	1/mrt	5	10	10	50	20	50
None	D1 ditch	3.928	3.928	3.928	3.928	3.928	3.928	3.928
50%		3.928	3.928	3.928	3.928	-	3.928	-
75%		3.928	3.928	3.928	3.928	-	3.928	-
90%		3.928	3.928	3.928	3.928	-	3.928	-
None	D1 stream	2.446	2.446	2.446	2.446	2.446	2.446	2.446
50%		2.446	2.446	2.446	2.446	-	2.446	-
75%		2.446	2.446	2.446	2.446	-	2.446	-
90%		2.446	2.446	2.446	2.446	-	2.446	-
None	D2 ditch	8.474	8.474	8.474	8.474	8.474	8.474	8.474
50%		8.474	8.474	8.474	8.474	-	8.474	-
75%		8.474	8.474	8.474	8.474	-	8.474	-
90%		8.474	8.474	8.474	8.474	-	8.474	-
None	D2 stream	5.449	5.449	5.449	5.449	5.449	5.449	5.449
50%		5.449	5.449	5.449	5.449	-	5.449	-
75%		5.449	5.449	5.449	5.449	-	5.449	-
90%		5.449	5.449	5.449	5.449	-	5.449	-
None	D3 ditch	-	0.2056	0.1091	0.1091	0.02346	0.05668	0.02346
50%		0.4615	0.1028	0.5451	0.05451	-	0.02833	-
75%		0.2308	0.0514	0.02726	0.02726	-	0.01417	-
90%		0.0923	0.02056	0.01091	0.010914	-	0.005667	-
None	D4 pond	-	0.3675	0.3659	0.3659	0.3633	0.3646	0.3633
50%		0.3671	0.347	0.3639	0.3639	-	0.3632	-
75%		0.3645	0.3633	0.3629	0.3629	-	0.3626	-
90%		0.3629	0.3625	0.3623	0.3623	-	0.3622	-

None	D4 stream	0.4432	0.4432	0.4432	0.4432	0.4432	0.4432	0.4432
50%		0.4432	0.4432	0.4432	0.4432	-	0.4432	-
75%		0.4432	0.4432	0.4432	0.4432	-	0.4432	-
90%		0.4432	0.4432	0.4432	0.4432	-	0.4432	-
None	D5 pond	-	0.639	0.6373	0.6373	0.6346	0.6359	0.6346
50%		0.6386	0.636	0.6352	0.6352	-	0.6345	-
75%		0.6358	0.6346	0.6342	0.6342	-	0.6338	-
90%		0.6342	0.6337	0.6335	0.6335	-	0.6334	-
None	D5 stream	0.8515	0.8515	0.8515	0.8515	0.8515	0.8515	0.8515
50%		0.8515	0.8515	0.8515	0.8515	-	0.8515	-
75%		0.8515	0.8515	0.8515	0.8515	-	0.8515	-
90%		0.8515	0.8515	0.8515	0.8515	-	0.8515	-
None	D6 ditch	3.309	3.309	3.309	3.309	3.309	3.309	3.309
50%		3.309	3.309	3.309	3.309	-	3.309	-
75%		3.309	3.309	3.309	3.309	-	3.309	-
90%		3.309	3.309	3.309	3.309	-	3.309	-
None	R1 pond	-	0.05231	0.04699	0.02695	0.01819	0.01574	0.01139
50%		0.05105	0.04285	0.0402	0.02015	-	0.01121	-
75%		0.04222	0.03815	0.03717	0.01676	-	0.008944	-
90%		0.03725	0.03625	0.03593	0.01509	-	0.0077	-
None	R1 stream	-	-	-	1.395	1.395	0.7266	0.7266
50%		-	-	-	1.395	-	0.7266	-
75%		-	-	-	1.395	-	0.7266	-
90%		-	-	-	1.395	-	0.7266	-
None	R3 stream	-	-	-	1.896	1.896	0.9946	0.9946
50%		-	-	-	1.896	-	0.9946	-
75%		-	-	-	1.896	-	0.9946	-
90%		-	-	-	1.896	-	0.9946	-
None	R4 stream	-	-	-	0.4911	0.4911	0.2565	0.2565
50%		-	-	-	0.4911	-	0.2565	-
75%		-	-	-	0.4911	-	0.2565	-
90%		-	-	-	0.4911	-	0.2565	-

Metabolites of Flufenacet

As worst case, only the highest intended application rate (2L GLOB1310aH/ha at pre-emergence) was used for the flufenacet metabolites PECsw of simulations, these simulations cover all other intended uses.

Table 0-17: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for FOE-sulfonic acid (M2) following single application of GLOB1310aH (2L/ha) to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	7 d- $PEC_{sw,twa}$ (µg/L)	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	8.8447	8.3813	7.5487	0.8553

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	7 d- $PEC_{sw,twa}$ (µg/L)	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 2					
Northern Europe	Jun-Sep	1.7281	1.6383	1.4771	0.1675
	Oct-Feb	4.2828	4.0605	3.6617	0.4151
Southern Europe	Jun-Sep	2.5797	2.4457	2.2055	0.2500
	Oct-Feb	3.4313	3.2531	2.9336	0.3326

Table 0-18: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for FOE-oxalate (M1) following single application of GLOB1310aH (2L/ha) to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	7 d- $PEC_{sw,twa}$ (µg/L)	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	7.2345	6.8554	6.1744	0.7645
Step 2					
Northern Europe	Jun-Sep	0.9976	0.9458	0.8530	0.1057
	Oct-Feb	2.4634	2.3356	2.1064	0.2609
Southern Europe	Jun-Sep	1.4862	1.4090	1.2708	0.1574
	Oct-Feb	1.9748	1.8723	1.6886	0.2092

Table 0-19: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for Thiadone (M9) following single application of GLOB1310aH (2L/ha) to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	7 d- $PEC_{sw,twa}$ (µg/L)	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	5.5381	5.2482	4.7268	0.0000
Step 2					
Northern Europe	Jun-Sep	1.0986	1.0411	0.9377	0.0000
	Oct-Feb	2.7232	2.5807	2.3243	0.0000
Southern Europe	Jun-Sep	1.6401	1.5543	1.3999	0.0000
	Oct-Feb	2.1817	2.0675	1.8621	0.0000

Table 0-20: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for Methylsulfide (M5) following single application of GLOB1310aH (2L/ha) to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	7 d- $PEC_{sw,twa}$ (µg/L)	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	7.8511	7.4400	6.7010	0.0000
Step 2					
Northern	Jun-Sep	1.5574	1.4759	1.3293	0.0000

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	7 d- $PEC_{sw,twa}$ (µg/L)	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Europe	Oct-Feb	3.8654	3.6585	3.2950	0.0000
Southern Europe	Jun-Sep	3.0928	2.9309	2.6398	0.0000
	Oct-Feb	3.0928	2.9309	2.6398	0.0000

8.9.2.3 $PEC_{sw/sed}$ of GLOB1310aH

The PECsw of the formulation GLOB1310aH following drift events were also calculated using the calculator tool from the FOCUS SWASH 5.3 model. The density of the product is 1.2282 kg/L so the application rate of the formulation is 2456.4 g/ha for 2.0L/ha and 1842.3 g/ha for 1.5L/ha. These PECsw were calculated for the ditch, pond and stream scenarios. On top, to allow for the 20 % spray drift contribution from the upstream catchment in the case of streams, the drift values of the calculator have been multiplied with a factor 1.2 for the stream scenario. The results of these calculations are provided below in the table below.

Table 0-21: Maximum PECsw for GLOB1310aH following a single application of 2.0 and 1.5L/ha to winter cereals

Cropping scenario	FOCUS scenario	1 m	3 m	5 m	10 m	20 m
		Max. PECsw (µg/L)	Max. PECsw (µg/L)	Max. PECsw (µg/L)	Max. PECsw (µg/L)	Max. PECsw (µg/L)
		No drift reduction nozzles				
Winter cereals, 1 x 2.0 L/ha	Ditch	15.7815	6.6814	4.2777	2.2687	1.1788
	Pond	0.8062	~~0.5792~~ 0.5702	0.4656	0.3348	0.2235
	Stream	15.7815	6.6814	4.2777	2.2687	1.1788
		18.9378*	8.0177*	5.1332*	2.7224*	1.4146*
		50% drift reduction nozzles				
	Ditch	-	-	2.13885	1.13435	0.5894
	Pond	-	-	0.2328	0.1674	0.11175
	Stream*	-	-	2.5666*	1.3612*	0.7073*
		75% drift reduction nozzles				
	Ditch	-	-	1.069425	0.567175	0.2947
	Pond	-	-	0.1164	0.0837	0.055875
	Stream*	-	-	1.2833*	0.6806*	0.35365*
		90% drift reduction nozzles				
	Ditch	-	-	0.42777	0.22687	0.11788
	Pond	-	-	0.04656	0.03348	0.02235
	Stream*	-	-	0.51332*	0.27224*	0.14146*
Winter cereals, 1		**No drift reduction nozzles**				

x 1.5 L/ha	Ditch	11.8361	5.0111	3.2083	1.7015	0.8841
	Pond	0.6046	0.4276	0.3492	0.2511	0.1676
	Stream	11.8361	5.0111	3.2083	1.7015	0.8841
		14.2033*	6.0133*	3.8499*	2.0418*	1.0609*
		50% drift reduction nozzles				
	Ditch	-	-	1.4651	0.777	0.4037
	Pond	-	-	0.15945	0.11465	0.07655
	Stream*	-	-	1.7581*	0.9324*	0.48445*
		75% drift reduction nozzles				
	Ditch	-	-	0.73255	0.3885	0.20185
	Pond	-	-	0.079725	0.057325	0.038275
	Stream*	-	-	0.87905*	0.4662*	0.242225*
		90% drift reduction nozzles				
	Ditch	-	-	0.29302	0.1554	0.08074
	Pond	-	-	0.03189	0.02293	0.01531
	Stream*	-	-	0.35162*	0.18648*	0.09689*

* Taking into account the 20% contribution from the upstream catchment

8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

Evaluation by zRMS	**Fate and behaviour in air (KCP 9.3)**
Comments	The data on the atmospheric degradation and behaviour for all two active substances follows the EU assessment and is therefore agreed by the zRMS.
Conclusion for exposure assessment	The vapour pressure at 20 °C of the active substance aclonifen is between 10^{-5} and 10^{-4} Pa. Due to the low potential of volatilisation as derived from physico-chemical properties, the environmental concentrations in air and the transport through air are considered negligible. The vapour pressure at 20 °C of the active substance flufenacet is between 10^{-5} and 10^{-4} Pa. Hence the active substance flufenacet is regarded as semivolatile (volatilisation only from plant surfaces). Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance flufenacet due to volatilization with subsequent deposition should be considered. However as GLOB1310aH is intended only for use as pre-emergence herbicide, corresponding to a crop interception of 0%, an assessment of volatilization with subsequent deposition from plant surfaces is not relevant.

Table 0-1 Summary of atmospheric degradation and behaviour - Aclonifen

Compound	Aclonifen
Direct photolysis in air	Not relevant

Quantum yield of direct phototransformation	Not relevant
Photochemical oxidative degradation in air	DT_{50} (h): 30.2 hours derived by AOP calculations (version 1.91) OH (12 h) concentration assumed = 0.5 x 10^6 radicals/cm³
Volatilisation	Vapour pressure (Pa): 1.6 x 10^{-5} (20 °C) Henry's Law Constant (Pa.m^3/mol): 3.03 x 10^{-3} (20 °C) From soil surfaces: less than 2.5 % of AR after 24 hours
Metabolites	Not applicable

The vapour pressure at 20 °C of the active substance Aclonifen is between 10^{-5} and 10^{-4} Pa. Due to the low potential of volatilisation as derived from physico-chemical properties, the volatilisation experiments available and the estimated photochemical transformation half-life (1.2 d), the environmental concentrations in air and the transport through air are considered negligible.

Table 0-2 Summary of atmospheric degradation and behaviour - Flufenacet

Compound	Flufenacet
Direct photolysis in air	Not relevant
Quantum yield of direct phototransformation	Not relevant
Photochemical oxidative degradation in air	DT_{50} (h): 4.7by the Atkinson model
Volatilisation	Vapour pressure (Pa): 9 x 10^{-5} (20 °C) Henry's Law Constant (Pa.m^3/mol): 9 x 10^{-43} (20 °C)
Metabolites	Not applicable

The vapour pressure at 20 °C of the active substance Flufenacet is between 10^{-5} and 10^{-4} Pa. Hence the active substance flufenacet is regarded as semi-volatile (volatilization only from plant surfaces). Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the compound due to volatilization with subsequent deposition should be considered. However as flufenacet formulated as GLOB1310aH is intended only for use as pre-emergence herbicide, corresponding to a crop interception of 0%, an assessment of volatilization with subsequent deposition from plant surfaces is not relevant.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	Owner
KCP 9.2.4	Ploem, J.P. Sanchez Lopez, A.	2021	Estimation of the PECgw of aclonifen, flufencate and relevant metabolites from the uses of GLOB1310aH Company Report No GLOB1310aHGW-CEU Globachem NV non GLP Unpublished	N	Globachem NV
KCP 9.2.5	Ploem, J.P. Sanchez Lopez, A.	2021	Estimation of the Predicted Environmental Concentrations in Surface Water (PECsw) and Sediment (PECsed) for Aclonifen, Flufenacet and relevant metabolites due to the use of GLOB1310aH Company Report No GLOB1310aHSW-CEU Globachem NV non GLP Unpublished	N	Globachem NV

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
/	/	/	None	/	/

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

List of data relied on not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Detailed evaluation of the new Annex II studies

No new Annex II studies are submitted within the frame of this application

Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)

No additional information is provided by the applicant. The files containing modelling data are provided only electronically.